

DRAFT FOR CONSULTATION

Therapeutic Products Bill

Government Bill

Hon Dr David Clark

Therapeutic Products Bill

Government Bill

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The Parliament of New Zealand enacts as follows:

1 Title

This Act is the Therapeutic Products Act **2018**.

2 Commencement

- (1) This Act comes into force on a date appointed by the Governor-General by Order in Council.
- (2) One or more Orders in Council may be made appointing different dates for different provisions.
- (3) To the extent that it is not previously brought into force under **subsection (1)**, this Act comes into force on [xx xx].

[Note for consultation draft: The date will be inserted in subsection (3) prior to the Bill being introduced. It is proposed that it will be approximately 2 years after the Bill receives the Royal assent.]

Part 1

Preliminary provisions

3 Purpose

The purpose of this Act is to protect personal and community health by—

- (a) ensuring acceptable safety, quality, and efficacy or performance of therapeutic products across their lifecycle; and
- (b) regulating the manufacture, import, promotion, supply, and administration or use of therapeutic products.

4 Principles guiding exercise of powers under this Act

The Regulator and any other person exercising a power under this Act must be guided by the purpose of this Act and the following principles:

- (a) the likely benefits of therapeutic products should outweigh the likely risks associated with them:
- (b) regulation of therapeutic products should—
 - (i) be proportionate to the risks posed by the products; and
 - (ii) support the timely availability of therapeutic products:
- (c) the administration of this Act should be carried on in an open and transparent manner:
- (d) there should be co-operation with overseas regulators, compliance with international obligations, and, if appropriate, alignment with international standards and practice.

5 Transitional, savings, and related provisions

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

6 Act binds the Crown

This Act binds the Crown.

Outline of regulatory scheme

7 Outline of regulatory scheme

- (1) This Act regulates therapeutic products in New Zealand.
- (2) **Sections 7 to 13** give a broad summary of the regulatory scheme. However, they are a guide only and do not affect the meaning of this Act.
- (3) The scheme consists of 2 broad components—
 - (a) product approval requirements; and
 - (b) controlled activity restrictions.
- (4) The product approval requirements regulate which products may be imported into, or supplied in, New Zealand.
- (5) The controlled activity restrictions regulate how therapeutic products (whether approved or not) can be dealt with. The controlled activities include manufacturing and supplying therapeutic products, prescribing and administering medicines, and using medical devices and other therapeutic products on patients.

8 What is covered by regulatory scheme

- (1) Therapeutic products are any products that are intended for use in, on, or in relation to humans for a therapeutic purpose, or for use as an active ingredient of a medicine (*see* **sections 15 and 16**).

- (2) They are divided into 4 types—medicines, active medicinal ingredients (known as AMIs), medical devices, and type-4 products (*see* **sections 18, 20, 21, and 23**).

9 Product approvals

- (1) Therapeutic products (other than AMIs) are regulated by means of product approvals.
- (2) Generally, a therapeutic product (other than an AMI) cannot be imported into New Zealand or supplied in New Zealand unless the product is approved (*see* **section 51**).
- (3) The process for getting a product approved is set out in **Part 4**. In broad terms, an applicant must satisfy the Regulator—
 - (a) about the quality, safety, and efficacy or performance of the product; and
 - (b) that the applicant is a suitable person to hold the approval.
- (4) Once a product is approved, the person to whom the approval is issued (known as the sponsor) is responsible for ensuring that the product complies with its approval and product standards and has ongoing obligations in relation to such things as safety monitoring, record keeping, and reporting (*see* **subpart 3 of Part 4**).
- (5) It is also possible for the Regulator to declare a product or class of products to be approval-exempt. Approval-exempt products may be imported or supplied without needing to be approved (*see* **section 51(1)(a)(ii)**).
- (6) The sponsor of an approval-exempt product (who will be determined by the Regulator when the product is declared to be approval-exempt) is subject to some of the ongoing obligations that apply to sponsors of approved products (*see* **sections 117 and 118**).
- (7) A person may be authorised (by a licence, permit, or provision of **subpart 3 of Part 3**) to import or supply a product without the product being approved (*see* **section 51(1)(b)**). They are authorised to do so only in accordance with the terms and conditions of the authorisation.

10 Controlled activities

- (1) This Act also regulates who is allowed to carry on certain activities involving therapeutic products (called controlled activities) and how those activities are carried on.
- (2) The controlled activities are listed in **section 53**. The kinds of activities that are regulated include—
 - (a) manufacturing:
 - (b) wholesale and non-wholesale supply:
 - (c) prescribing, administering, and possessing medicines:
 - (d) using medical devices and type-4 products on patients:

- (e) issuing standing orders:
- (f) conducting clinical trials:
- (g) carrying on a pharmacy business.

However, exactly what constitutes a controlled activity varies depending on the type and category of product and the circumstances in which the activity is carried on.

- (3) The regulation of controlled activities applies to all therapeutic products, and applies regardless of whether they are approved, approval-exempt, or unapproved.
- (4) It is an offence to carry on a controlled activity unless authorised to do so by a licence, permit, or provision of **subpart 3 of Part 3** (*see section 53*).
- (5) If a product poses a very significant risk of harm, regulations may declare it to be a prohibited product (*see section 25*). **Section 81** then prohibits anyone from importing, manufacturing, supplying, administering or using, or being in possession of it without a permit.

11 Authorisations: subpart 3 of Part 3, licences, and permits

- (1) **Subpart 3 of Part 3** authorises people to carry on controlled activities in various circumstances. This includes authorisations for pharmacists, health practitioners, veterinarians, and related workers. **Section 79** allows regulations to be made authorising other people to carry on controlled activities.
- (2) Anyone who is covered by an authorisation in **subpart 3 of Part 3** may carry on the activity in accordance with the terms of the authorisation without needing a licence or permit.
- (3) A person may be authorised to carry on a controlled activity by a licence or permit. A licence or permit applies only to the controlled activities that are specified in it and only to the therapeutic products that are covered by the licence or permit. A licence or permit is also subject to its terms and conditions (*see sections 125 and 133*).
- (4) The requirements for getting a licence or permit are set out in **Part 5**.
- (5) Anyone who is authorised to carry on a controlled activity must also comply with obligations relating to matters such as—
 - (a) when, where, and how the activity is carried on:
 - (b) packaging and labelling:
 - (c) product and consumer information:
 - (d) storage, handling, security, transport, and disposal:
 - (e) record keeping, auditing, and giving information to the Regulator.

The details of these obligations are set out in the regulations (*see section 55*).

12 Obligations of other people

- (1) This Act also imposes obligations on people who, in the course of business, import, supply, administer or use on patients, or have possession of any therapeutic products, even if they are not carrying on a controlled activity (*see section 55* and the regulations made under it).
- (2) These obligations may relate to the same matters as are referred to in **section 11(5)**, but the obligations on these people are generally less onerous than the obligations of people carrying on controlled activities.
- (3) This Act also imposes restrictions on the advertising of therapeutic products and prohibits things such as tampering with, or making misrepresentations about, therapeutic products (*see subpart 4 of Part 3*). These provisions apply to everyone.

13 Administration of regulatory scheme

- (1) The regulatory scheme is administered by the chief executive of the Ministry that administers this Act, who is known as the Regulator.
- (2) The Regulator is responsible for approving products, monitoring product safety, licensing, and administering and enforcing this Act.
- (3) The Regulator's powers and duties are set out in **Parts 6 and 7**.

Part 2 Interpretation

Subpart 1—General

14 Interpretation

In this Act, unless the context otherwise requires,—

this Act includes the regulations, the rules, and any Regulator's notices
active moiety, in **subpart 4 of Part 4**, has the meaning set out in **section 120**

administer, in relation to a medicine, has the meaning set out in **section 26**

advertisement has the meaning set out in **section 82(1)**

advertising remediation order has the meaning set out in **section 166(2)**

AMI (which is an abbreviation for active medicinal ingredient) has the meaning set out in **section 20**

analyst means—

- (a) the person designated under **section 187(1)(b)** as the analyst in charge of a laboratory designated under **section 187(1)(a)** as a recognised laboratory; or
- (b) a worker nominated under **section 187(2)** as an analyst

approval, in relation to a therapeutic product, means an approval granted under **section 94** for the product, including any conditions to which the approval is subject under **section 105**

approval-exempt product has the meaning set out in **section 24(b)**

approved medical device means a medical device that is an approved product

approved medicine means a medicine that is an approved product

approved product has the meaning set out in **section 24(a)**

approved type-4 product means a type-4 product that is an approved product

authorised prescriber, for a medicine, means—

- (a) a health practitioner prescriber for the medicine; or
- (b) a veterinarian; or
- (c) any other person who is authorised by a licence, permit, or provision of **subpart 3 of Part 3** to prescribe the medicine

believe means to believe on reasonable grounds

business means a business, professional practice, or other undertaking, whether or not carried on for gain or reward

category, in relation to a medicine, means a category referred to in **section 19**

category 1 AMI means an AMI if any medicine containing the AMI is (or, if manufactured, would be) a category 1 medicine

clinical trial has the meaning set out in **section 27**

complying prescription has the meaning set out in **section 38(2)**

complying special clinical needs supply authority has the meaning set out in **section 39(2)**

complying standing order has the meaning set out in **section 40(2)**

compound has the meaning set out in **section 28**

controlled activity has the meaning set out in **section 53(2)**

Customs means the New Zealand Customs Service under the Customs and Excise Act 2018

directions order has the meaning set out in **section 168(2)**

dispense has the meaning set out in **section 29**

distribute, in relation to a communication, has the meaning set out in **section 82(4)**

enforceable undertaking means an undertaking that has been accepted by the Regulator under **section 223** and is in force

ethics approval means an approval granted by an ethics approval entity

ethics approval entity means—

- (a) a Health and Disability Ethics Committee established under section 11 of the New Zealand Public Health and Disability Act 2000; or
- (b) a person or body that—
 - (i) performs functions similar to those of a committee referred to in **paragraph (a)**; and
 - (ii) the Regulator has, by a Regulator’s notice, designated as an ethics approval entity

evidential material, in **subpart 2 of Part 6**, has the meaning set out in **section 183**

exemption means an exemption granted under **section 264**

fit and proper person, *see* **section 47**

grounds to cancel, in relation to an approval, has the meaning set out in **section 108**

grounds to suspend or cancel, in relation to a licence or permit, has the meaning set out in **section 141 or 142**

harm means harm to personal or community health

health practitioner means a person who—

- (a) is a health practitioner as defined in section 5 of the Health Practitioners Competence Assurance Act 2003; and
- (b) holds a current practising certificate under that Act

health practitioner prescriber, for a medicine, means a health practitioner whose scope of practice includes the prescribing of the medicine

health practitioner worker, in relation to a licensee, means a health practitioner who works for the licensee and, in the course of that work, carries on or does anything authorised by the licence or by a provision of **subpart 3 of Part 3**

import has the meaning set out in **section 30**

induce includes to request, instruct, persuade, encourage, assist, or coerce

infringement circumstances has the meaning set out in **section 249(1)**

infringement fee has the meaning set out in **section 250(1)**

infringement fine has the meaning set out in **section 250(1)**

infringement notice means a notice issued under **section 253**

infringement offence has the meaning set out in **section 249(2)**

innovative medicine application, in **subpart 4 of Part 4**, has the meaning set out in **section 120**

intended for use for a therapeutic purpose has the meaning set out in **section 15(2)**

intent to deceive includes intent to do 1 or more of the following:

- (a) deceive the Regulator or any other person:
- (b) wrongfully obtain a material benefit or avoid a material detriment:
- (c) frustrate the administration of this Act

investigative purposes, in **subpart 2 of Part 6**, has the meaning set out in **section 183**

issuing officer, in **subpart 2 of Part 6**, has the meaning set out in **section 183**

level XX offence (where XX is A1, A2, A3, B1, B2, or B3) means a contravention of a provision of this Act that is stated to be a level A1, A2, A3, B1, B2, or B3 offence (because of the circumstances in which it is committed)

licence means a licence granted under **section 127**

licensee means the holder of a licence

limitation includes a prohibition, restriction, or condition

limited-access medicine has the meaning set out in **section 173(2)(a)(i)**

limited-access patient has the meaning set out in **section 173(2)**

major change has the meaning set out in **section 100**

make publicly available, in relation to the Regulator, has the meaning set out in **section 219**

manufacture has the meaning set out in **section 31(1)**

manufacturer has the meaning set out in **section 31(2)**

medical device has the meaning set out in **section 21**

medicine has the meaning set out in **section 18**

medicine access limitation order has the meaning set out in **section 173(2)**

Ministry means the department (within the meaning of section 27A of the State Sector Act 1988) that, with the authority of the Prime Minister, is responsible for the administration of this Act

misleading information means information that is false, that is misleading in a material particular, or that is misleading because of the omission of a material particular

non-wholesale supply has the meaning set out in **section 43(3)**

notify means to give notice in writing to a person

opportunity to comment has the meaning set out in **section 206**

original decision has the meaning set out in **section 201**

overseas organisation means an overseas or international organisation that has a function relating to therapeutic products, health, or law enforcement

overseas regulator means a body in another country that performs functions that correspond with, or are similar to, any of those of the Regulator under this Act

oversupplied person has the meaning set out in **section 172(2)**

permit means a permit granted under **section 134**

permit holder means the holder of a permit

person in the supply chain has the meaning set out in **section 44(2)**

pharmacist means a health practitioner who is, or is deemed to be, registered with the Pharmacy Council (as established by section 114(5) of the Health Practitioners Competence Assurance Act 2003) under that Act as a practitioner of the profession of pharmacy

pharmacy activity has the meaning set out in **section 36(3)**

pharmacy business has the meaning set out in **section 36(1)**

pharmacy licence means a licence that authorises the licensee to carry on a pharmacy business

pharmacy worker has the meaning set out in **section 37(1)**

premises restriction order has the meaning set out in **section 164(2)**

prepare for administration has the meaning set out in **section 26(2)**

prepare for use has the meaning set out in **section 46(2)**

prescribe, in relation to a medicine, has the meaning set out in **section 38(3)**

prescription has the meaning set out in **section 38(1)**

product prohibition order has the meaning set out in **section 170(2)**

prohibited product has the meaning set out in **section 25**

protected active ingredient information, in **subpart 4 of Part 4**, has the meaning set out in **section 120**

protection period, in **subpart 4 of Part 4**, has the meaning set out in **section 120**

qualified, in relation to a pharmacy worker, has the meaning set out in **section 37(2)**

recall order has the meaning set out in **section 162(2)**

regulations means regulations made under **section 261**

Regulator means the chief executive of the Ministry

Regulator's Internet site means an Internet site maintained by or on behalf of the Regulator for the purposes of this Act

Regulator's notice means a notice made under **section 263**

regulatory entity means any of the following:

- (a) the New Zealand Police:

- (b) the Serious Fraud Office:
- (c) the chief executive of the Ministry (other than in their capacity as the Regulator):
- (d) a responsible authority under the Health Practitioners Competence Assurance Act 2003:
- (e) the Pharmaceutical Management Agency (Pharmac) under the New Zealand Public Health and Disability Act 2000:
- (f) the Health Quality and Safety Commission under the New Zealand Public Health and Disability Act 2000:
- (g) the Inland Revenue Department:
- (h) the Accident Compensation Corporation under the Accident Compensation Act 2001:
- (i) the Health and Disability Commissioner under the Health and Disability Commissioner Act 1994:
- (j) the department in relation to any of the following:
 - (i) the Agricultural Compounds and Veterinary Medicines Act 1997:
 - (ii) the Biosecurity Act 1993:
 - (iii) the Customs and Excise Act 2018:
 - (iv) the Food Act 2014:
 - (v) the Hazardous Substances and New Organisms Act 1996:
 - (vi) the Health Practitioners Competence Assurance Act 2003:
 - (vii) the Human Assisted Reproductive Technology Act 2004:
 - (viii) the Human Tissue Act 2008:
 - (ix) the Misuse of Drugs Act 1975:
 - (x) the Psychoactive Substances Act 2013:
 - (xi) the Radiation Safety Act 2016

regulatory order means any of the following:

- (a) a recall order:
- (b) a premises restriction order:
- (c) an advertising remediation order:
- (d) a directions order:
- (e) a product prohibition order:
- (f) a medicine access limitation order

relevant thing, in **subpart 2 of Part 6**, has the meaning set out in **section 183**

responsible manufacturer has the meaning set out in section 31(3)

responsible person, in relation to a licence, means an individual named in the licence as a responsible person

rules means rules made by the Regulator under **section 262**

scope of practice, for a health practitioner, means the practitioner's scope of practice under the Health Practitioners Competence Assurance Act 2003

senior manager has the meaning set out in **section 48**

special clinical needs supply authority has the meaning set out in **section 39(1)**

specified fee, for a matter, means the fee (if any) specified for the matter by the regulations referred to in **section 257**

specified product standard, for a therapeutic product, means the product standards (if any) specified in the rules referred to in **section 96** for that product

sponsor,—

- (a) in relation to an approved product, means—
 - (i) the person to whom the approval was granted under **section 94(3)**; or
 - (ii) if the approval has been transferred under section 102, the person to whom it was transferred:
- (b) in relation to an approval-exempt product, means the person specified as the sponsor in accordance with **section 115(1)**

standing order has the meaning set out in **section 40(1)**

state of mind, in relation to a person, includes their knowledge, intention, opinion, belief, or purpose and their reasons for that intention, opinion, belief, or purpose

supply has the meaning set out in **section 42**

supply chain activity has the meaning set out in **section 44(1)**

supply-restricted device has the meaning set out in **section 22(1)**

supply restriction has the meaning set out in **section 22(1)**

take overseas has the meaning set out in **section 45**

tamper with has the meaning set out in **section 84(1)**

therapeutic product has the meaning set out in **section 16**

therapeutic purpose has the meaning set out in **section 15**

type, in relation to a therapeutic product, means a type of therapeutic product specified in **section 17**

type-4 product has the meaning set out in **section 23**

unapproved product has the meaning set out in **section 24(c)**

unprofessional, in relation to a health practitioner, means not in accordance with the standards of clinical competence, cultural competence, and ethical conduct set under section 118(i) of the Health Practitioners Competence Assurance Act 2003 by the authority for the practitioner's profession

use, in relation to a medical device or type-4 product, has the meaning set out in **section 46(1)**

use-restricted device has the meaning set out in **section 22(2)**

use restriction has the meaning set out in **section 22(2)**

veterinarian has the same meaning as in section 4 of the Veterinarians Act 2005

wholesale supply has the meaning set out in **section 43(2)**

work has the meaning set out in **section 49(1)**

worker has the meaning set out in **section 49(2)**.

Subpart 2—Therapeutic products

15 Meaning of therapeutic purpose

- (1) The following are **therapeutic purposes**:
 - (a) preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for a disease, ailment, defect, or injury:
 - (b) influencing, inhibiting, or modifying a human physiological process:
 - (c) testing the susceptibility of humans to a disease or an ailment:
 - (d) influencing, controlling, or preventing human conception:
 - (e) testing for human pregnancy:
 - (f) investigating, replacing, modifying, or supporting part of a human's anatomy:
 - (g) supporting or sustaining human life:
 - (h) disinfecting medical devices:
 - (i) a purpose connected with a purpose referred to in **paragraphs (a) to (h)**.
- (2) Something is **intended for use for a therapeutic purpose** if it is, or is in a class of things that are,—
 - (a) ordinarily used for that purpose; or
 - (b) intended by the responsible manufacturer to be used for that purpose; or
 - (c) represented as being for use for that purpose; or
 - (d) likely (because of the way in which it is presented or for any other reason) to be used for that purpose.

16 Meaning of therapeutic product

- (1) A product is a **therapeutic product** if—
- (a) it is intended for use in, on, or in relation to humans for a therapeutic purpose; or
 - (b) it is specified in the regulations to be a therapeutic product; or
 - (c) it—
 - (i) is not a therapeutic product under **paragraph (a) or (b)**; but
 - (ii) is intended for use as an active ingredient of a medicine.
- (2) A naturally occurring thing that might not otherwise be considered to be a product may become a product if it is changed from its naturally occurring state (and, having become a product, if **subsection (1)(a), (b), or (c)** applies to it, it would be a therapeutic product).
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Example

Human blood is not generally regarded as a product. However, if a person donates blood to the NZ Blood Service, the collected blood would become a product. As the donated blood is intended for use for a therapeutic purpose, it would be a therapeutic product.

- (3) However, a product that would otherwise be a therapeutic product under **subsection (1)(a)** is not a therapeutic product if it is a natural health product.

[Note for consultation draft: The government is considering options for the regulation of natural health products and intends to exclude them from the Bill. However, the definition of natural health product and the exact mechanism by which they will be excluded from the Bill are yet to be determined. Exclusion from the definition of therapeutic product, as provided by subsection (3), is one of the options being considered.]

- (4) A product that would otherwise be a therapeutic product under **subsection (1)(a) or (c)** is not a therapeutic product if it is specified in the regulations to not be a therapeutic product.

17 Types of therapeutic products

There are 4 **types** of therapeutic products—

- (a) medicines:
- (b) AMIs:
- (c) medical devices:
- (d) type-4 products.

18 Meaning of medicine

- (1) A therapeutic product is a **medicine** if—
- (a) it—

- (i) is a therapeutic product under **section 16(1)(a) or (b)**; and
 - (ii) achieves, or is likely to achieve, its principal intended action—
 - (A) by pharmacological, immunological, or metabolic means; or
 - (B) by means of the action of something that comprises, contains, or is derived from human or animal cells or tissues; or
 - (b) it is specified in a Regulator’s notice to be a medicine.
- (2) However, a therapeutic product that would otherwise be a medicine under **subsection (1)(a)** is not a medicine if it is specified in a Regulator’s notice to be an AMI, a medical device, or a type-4 product.

19 Categories of medicine

- (1) There are 4 categories of medicines, being categories 1, 2, 3, and 4.
- (2) The regulations must provide for the categorisation of medicines (and must do so in a way that results in every medicine being in one of the 4 categories).
- (3) The regulations may provide for the Regulator to categorise medicines by Regulator’s notice.
- (4) A reference to a **category X** medicine (where X is the number 1, 2, 3, or 4) is a reference to a medicine that is in the category of that number.

20 Meaning of AMI (active medicinal ingredient)

- (1) A therapeutic product is an **AMI** if—
 - (a) it is a therapeutic product under **section 16(1)(c)**; or
 - (b) it is specified in a Regulator’s notice to be an AMI.
- (2) However, a therapeutic product that would otherwise be an AMI under **subsection (1)(a)** is not an AMI if it is specified in a Regulator’s notice to be a medicine, a medical device, or a type-4 product.

21 Meaning of medical device

- (1) A therapeutic product is a **medical device** if—
 - (a) it—
 - (i) is a therapeutic product under **section 16(1)(a) or (b)**; and
 - (ii) achieves, or is likely to achieve, its principal intended action by means other than—
 - (A) pharmacological, immunological, or metabolic means; or
 - (B) the action of something that comprises, contains, or is derived from human or animal cells or tissues;
 - (b) (although its function may be assisted by pharmacological, immunological, or metabolic processes or by the action of something

that comprises, contains, or is derived from human or animal cells or tissues); or

- (b) it is specified in a Regulator’s notice to be a medical device.
- (2) However, a therapeutic product that would otherwise be a medical device under **subsection (1)(a)** is not a medical device if it is specified in a Regulator’s notice to be a medicine, an AMI, or a type-4 product.

22 Supply-restricted devices and use-restricted devices

- (1) A medical device is a **supply-restricted device** if the regulations—
- (a) declare it to be a supply-restricted device; and
 - (b) specify restrictions that apply to the non-wholesale supply of the device (**supply restrictions**).
- (2) A medical device is a **use-restricted device** if the regulations—
- (a) declare it to be a use-restricted device; and
 - (b) specify restrictions that apply to the use of the device on persons (**use restrictions**).
- (3) Regulations specifying supply or use restrictions may (without limitation) relate to any of the following:
- (a) persons who may, or must not, supply or use the device;
 - (b) circumstances in which the device may, or must not, be supplied or used;
 - (c) how the device may, or must not, be supplied or used.

23 Meaning of type-4 product

A therapeutic product is a **type-4 product** if it is specified in a Regulator’s notice to be a type-4 product.

24 Meanings of approved product, approval-exempt product, and unapproved product

A medicine, medical device, or type-4 product is—

- (a) an **approved product** if it is approved under **subpart 1 of Part 4** and is not a prohibited product; or
- (b) an **approval-exempt product** if it is declared to be an approval-exempt product under **section 114** and is not a prohibited product; or
- (c) an **unapproved product** if it is not an approved product, an approval-exempt product, or a prohibited product.

25 Meaning of prohibited product

- (1) A therapeutic product is a **prohibited product** if it is specified in the regulations to be a prohibited product.

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- (2) The Minister must not recommend the making of regulations specifying a product to be a prohibited product unless satisfied that—
- (a) the product poses a significant risk of death or serious harm; and
 - (b) that risk cannot be adequately managed by the exercise of the Regulator's powers under this Act.

Subpart 3—Activities

26 Meanings of administer and prepare for administration

- (1) To **administer** a medicine means to do either or both of the following:
- (a) prepare the medicine for administration:
 - (b) administer the medicine to a person or an animal—
 - (i) by introducing it into their body (orally, by injection, or in any other way); or
 - (ii) by external application.
- (2) To **prepare for administration**, in relation to a medicine, includes the following:
- (a) to dissolve, disperse, dilute, or mix the medicine in or with another substance as an administration medium:
 - (b) to mix the medicine with another medicine to be administered at the same time.

27 Meaning of clinical trial

A **clinical trial** of a therapeutic product means an investigation—

- (a) that involves administering the product to, or using it on, 1 or more individuals (**subjects**); and
- (b) that is undertaken to obtain information about,—
 - (i) for a medicine, its quality, safety, or efficacy or performance by doing 1 or more of the following:
 - (A) discovering or verifying its clinical, pharmacological, or other pharmacodynamic effects:
 - (B) identifying any adverse reactions to it:
 - (C) studying its absorption, distribution, metabolism, or excretion; or
 - (ii) for a medical device or type-4 product, its quality, safety, or efficacy or performance; and
- (c) to which 1 or more of the following apply:

- (i) the assignment of each subject to a particular therapeutic strategy is decided in advance and does not fall within normal clinical practice:
- (ii) the decision to administer or use the product is taken together with the decision to include the subject in the study:
- (iii) diagnostic or monitoring procedures additional to those used in normal clinical practice are applied to the subjects.

28 Meaning of compound

- (1) To **compound** a medicine means to produce a permitted quantity of the medicine ready for supply to a particular identified patient in response to a request for that supply.
- (2) A **permitted quantity** of a medicine means,—
 - (a) if the rules specify a maximum compoundable quantity for the medicine, an amount that does not exceed the specified quantity; or
 - (b) otherwise, not more than the patient reasonably needs for the period in respect of which the medicine is to be supplied.
- (3) Compounding a medicine is part of manufacturing the medicine (*see section 32(2)*).

29 Meaning of dispense

- (1) To **dispense** a medicine means to bring the medicine to a state ready for immediate supply to a particular identified patient in response to a request for that supply.
- (2) Preparing a medicine for immediate administration is not dispensing.
- (3) Dispensing a medicine is part of manufacturing the medicine (*see section 32(2)*).

30 Meaning of import

- (1) To **import** a therapeutic product means to bring the product into New Zealand.
- (2) If a therapeutic product is imported, each of the following are taken to import it:
 - (a) a person who does the physical activity of importing the product:
 - (b) a person who arranges for, or causes, the product to be imported:
 - (c) a consignee of the product:
 - (d) a person who—
 - (i) owns, has a beneficial interest in, or is entitled to possession of, the product at the time it is imported; or
 - (ii) becomes the owner of, entitled to possession of, or beneficially interested in the product while it is subject to the control of Cus-

toms (as defined in section 6 of the Customs and Excise Act 2018).

31 Meanings of manufacture, manufacturer, and responsible manufacturer

- (1) To **manufacture** a therapeutic product has the meaning set out in,—
 - (a) for a medicine, **section 32**;
 - (b) for an AMI, **section 33**;
 - (c) for a medical device, **section 34**;
 - (d) for a type-4 product, **section 35**.
- (2) A person is a **manufacturer** of a therapeutic product if the person does anything that is part of manufacturing the product.
- (3) The **responsible manufacturer** of a therapeutic product is the person who is in fact primarily responsible for the manufacture of the product.
- (4) In determining who is the responsible manufacturer of a medicine or an AMI, the following are relevant considerations:
 - (a) who transforms the starting materials into the final product;
 - (b) who is responsible for overall quality assurance and quality control in relation to the manufacture of the product;
 - (c) if the product is, or is intended to be, released into the supply chain, whose name or trade mark the product is, or is to be, supplied under.
- (5) In determining who is the responsible manufacturer of a medical device or type-4 product—
 - (a) a person may be the responsible manufacturer whether or not they personally undertake the manufacture of the product; and
 - (b) the following are relevant considerations:
 - (i) who initiated the manufacture of the product;
 - (ii) if the product is, or is intended to be, released into the supply chain, whose name or trade mark the product is, or is to be, supplied under;
 - (iii) who is responsible for overall quality assurance and quality control in relation to the manufacture of the product.
- (6) The matters listed in **subsections (4)(a) to (c) and (5)(b)**—
 - (a) are relevant but not determinative considerations; and
 - (b) do not limit the matters that may be taken into account in determining who is the responsible manufacturer of a product.
- (7) If a medical device is remanufactured (as defined in **section 34(4)**),—
 - (a) the person who was the responsible manufacturer of the original device ceases to be the responsible manufacturer; and

- (b) the person who is primarily responsible for the remanufacture is the responsible manufacturer of the remanufactured device.

32 Meaning of manufacture, for medicine

- (1) To **manufacture** a medicine means—
 - (a) to produce the medicine; or
 - (b) to do anything that is part of the process of—
 - (i) producing the medicine; or
 - (ii) bringing the medicine to its final state (including testing, sterilising, releasing for supply, packaging, or labelling the medicine).

Compounding or dispensing part of manufacture

- (2) Compounding or dispensing a medicine is part of manufacturing the medicine.

Preparing for administration not part of manufacture

- (3) Preparing a medicine for administration is not part of manufacturing the medicine if the preparation is done—
 - (a) in accordance with the responsible manufacturer’s product information; or
 - (b) by, or in accordance with the directions of, an authorised prescriber for the medicine.

Cell and tissue medicines

- (4) In relation to a medicine that comprises, contains, or is derived from human or animal cells or tissues, to manufacture the medicine includes the following—
 - (a) to procure the cells or tissues (including to remove them from their natural state so as to make them into a product (*see section 16(2)*));
 - (b) to test, preserve, or bank or otherwise store the cells or tissues or their derivatives;
 - (c) to process, engineer, or otherwise modify the cells or tissues or their derivatives.

33 Meaning of manufacture, for AMI

To **manufacture** an AMI means—

- (a) to produce the AMI; or
- (b) to do anything that is part of the process of—
 - (i) producing the AMI; or
 - (ii) bringing the AMI to its final state ready for use in the manufacture of medicines (including testing, sterilising, releasing for supply, packaging, or labelling the AMI).

34 Meaning of manufacture, for medical device

- (1) To **manufacture** a medical device means—
- (a) to produce the device; or
 - (b) to do anything that is part of the process of—
 - (i) producing the device; or
 - (ii) bringing the device to its final state (including testing, sterilising, releasing for supply, packaging, or labelling the device); or
 - (c) to do anything that is part of the process of remanufacturing the device.

Software

- (2) In relation to a device that is or includes software, to produce the device includes to develop the software.

Preparing for use not part of manufacture

- (3) If a medical device has been supplied by its responsible manufacturer as being in its final state but needs to be prepared for use, preparing it for use is not part of manufacturing the device if the preparation—
- (a) is done in accordance with the responsible manufacturer's product information; and
 - (b) does not constitute remanufacturing the device.

Remanufacture

- (4) If a medical device has been supplied by its responsible manufacturer as being in its final state (whether or not it has been used), to **remanufacture** the device means to alter, refurbish, recondition, or otherwise further process the device so as to—
- (a) change the purpose for which it is intended to be used; or
 - (b) enable it to be used in a way that is materially different from that intended by the responsible manufacturer of the original device; or
 - (c) if it was originally manufactured as a single-use-only device, enable it to be re-used; or
 - (d) make it into a different medical device; or
 - (e) make any other change to it that would be a major change if it were an approved product.
- (5) However, a person does not remanufacture a medical device (other than a single-use only device) merely by cleaning it, carrying out repairs and maintenance, or undertaking similar processes, to enable the continued use of the device in the originally intended manner.

35 Meaning of manufacture, for type-4 product

- (1) To **manufacture** a type-4 product means—

- (a) to produce the product; or
- (b) to do anything that is part of the process of—
 - (i) producing the product; or
 - (ii) bringing the product to its final state (including testing, sterilising, releasing for supply, packaging, or labelling the product).
- (2) Preparing a type-4 product for use is not part of manufacturing the product if the preparation is done in accordance with the responsible manufacturer's product information.

36 Meanings of pharmacy business and pharmacy activity

- (1) A business is a **pharmacy business** if its activities include 1 or more of the following:
 - (a) compounding medicines for non-wholesale supply;
 - (b) dispensing medicines for non-wholesale supply;
 - (c) supplying category 1 or 2 medicines by non-wholesale supply.
- (2) However, a business is not a pharmacy business if—
 - (a) it is the professional practice of a health practitioner or veterinarian in which medicines are dispensed or supplied under the authorisations provided by **sections 61 to 70**; or
 - (b) it is a business of a kind specified in the regulations not to be a pharmacy business.
- (3) For a pharmacy business, the following are **pharmacy activities**:
 - (a) the activities listed in **subsection (1)**;
 - (b) supplying category 3 medicines by non-wholesale supply;
 - (c) supplying medicines and medical devices by wholesale supply in circumstances permitted by the regulations.
- (4) If a business is a pharmacy business under **subsection (1)**, then all of the pharmacy activities it carries on are taken to be part of the pharmacy business (and therefore subject to the terms and conditions of the licence).
- (5) However, if the business also carries on other activities that are not pharmacy activities, the business is only a pharmacy business to the extent of its pharmacy activities.

37 Meanings of pharmacy worker and qualified

- (1) A **pharmacy worker** is a person who works in a pharmacy business but is not a pharmacist.
- (2) A pharmacy worker is **qualified** to carry on a pharmacy activity in relation to a medicine if the worker meets the qualification, training, and competency requirements specified in the rules for that pharmacy activity in relation to that medicine.

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- (3) The rules may specify either or both of the following:
- (a) qualification, training, and competency requirements for pharmacy workers;
 - (b) levels of supervision under which a qualified pharmacy worker may carry on pharmacy activities (for the purposes of **section 60**).

38 Meanings of prescription, complying prescription, and prescribe

- (1) A **prescription** is a direction that sets out details of a particular medicine that is to be administered by or to a particular identified person or animal (the **patient**).
- (2) A prescription for a medicine is a **complying prescription** if—
- (a) it is issued by a person who is authorised to issue it; and
 - (b) it is made in accordance with any requirements for complying prescriptions specified in the regulations; and
 - (c) no expiry event specified in the regulations has occurred in relation to it.
- (3) To **prescribe** a medicine means to issue a prescription for that medicine.
- (4) Subject to the regulations, a prescription may be issued orally, in writing, or in any other form.
- (5) A person does not issue a prescription merely by doing either of the following:
- (a) making a record of a prescription that was issued orally;
 - (b) after supplying some but not all of the medicine specified in a prescription, making a record setting out that the rest of the medicine remains to be supplied.
- (6) Regulations for the purposes of **subsection (2)(b)** may (without limitation) relate to any of the following:
- (a) circumstances in which a prescription may, or must not, be issued;
 - (b) the form of a prescription;
 - (c) the content of a prescription;
 - (d) how a prescription is to be issued.

39 Meanings of special clinical needs supply authority and complying special clinical needs supply authority

- (1) A **special clinical needs supply authority** is a document that—
- (a) states that the person issuing it has determined that a particular identified person or animal (the **patient**) has a special clinical need for a specified unapproved product; and
 - (b) is issued for the purpose of enabling the procurement and supply of that product to meet that need.

- (2) A special clinical needs supply authority is a **complying special clinical needs supply authority** if—
- (a) it is issued by a person who is authorised to issue it; and
 - (b) it is made in accordance with any requirements for complying special clinical needs supply authorities in the regulations; and
 - (c) no expiry event specified in the regulations has occurred in relation to it.
- (3) Regulations for the purposes of **subsection (2)(b)** may (without limitation) relate to any of the following:
- (a) circumstances in which a special clinical needs supply authority may, or must not, be issued;
 - (b) the form of a special clinical needs supply authority;
 - (c) the content of a special clinical needs supply authority;
 - (d) how a special clinical needs supply authority is to be issued.

40 Meanings of standing order and complying standing order

- (1) A **standing order** is an order that authorises a person to do 1 or more of the following:
- (a) supply an approved or approval-exempt category 1, 2, or 3 medicine by non-wholesale supply (for the purposes of **section 53(1) and (2)(c)(i) and (ii)**);
 - (b) supply an approved or approval-exempt category 1 medicine by non-wholesale supply without a prescription (for the purposes of **section 54**);
 - (c) administer an approved or approval-exempt category 1 medicine (for the purposes of **section 53(1) and (2)(f)**).
- (2) A standing order is a **complying standing order** if—
- (a) it is issued by a person who is authorised to issue it; and
 - (b) it is made in accordance with any requirements for complying standing orders in the regulations.
- (3) Regulations for the purposes of **subsection (2)(b)** may (without limitation) relate to any of the following:
- (a) circumstances in which a standing order may, or must not, be issued;
 - (b) the form of a standing order;
 - (c) the content of a standing order;
 - (d) how a standing order is to be issued.

41 Effect of complying standing order

- (1) A complying standing order—
- (a) takes effect at the time it is made; and

- (b) remains in force until the first of the following occurs:
 - (i) if it includes an expiry date, the end of that day;
 - (ii) the issuer of the order revokes it;
 - (iii) a revocation event specified in the regulations.
- (2) A complying standing order authorises a person specified in it to supply or administer (as specified in the order) an approved or approval-exempt medicine specified in the order in accordance with the terms and conditions of the order.
- (3) However, a complying standing order has effect subject to the regulations.
- (4) Regulations for the purposes of **subsection (3)** may (without limitation) relate to any of the following:
 - (a) the effect of a complying standing order if the issuer ceases to be authorised to issue it;
 - (b) the effect of a complying standing order if a person authorised by the order ceases to be a person who may be authorised by an order;
 - (c) whether a complying standing order may be issued by a person in their capacity as the holder of a particular office or position and, if so, the effect of their ceasing to hold that office or position.
- (5) For the purposes of **sections 239 to 241**, a person who is authorised by a complying standing order to do something is taken to be the agent of the person who issued the order.

42 Meaning of supply

- (1) To **supply** a therapeutic product means to supply the therapeutic product to another person (whether that person is in New Zealand or elsewhere).
- (2) If a person sends a therapeutic product from a place in New Zealand to themselves at a place outside New Zealand, they are taken to supply the product (even though the supplier and recipient are the same person).
- (3) However, supply does not include administering a medicine or using a medical device or type-4 product on a patient.
- (4) In determining whether a person has supplied a therapeutic product, the following are immaterial:
 - (a) the quantity of the product;
 - (b) the purpose for which the product is supplied;
 - (c) whether the recipient pays for, or gives something in exchange for, the product or is liable to do so;
 - (d) whether the recipient acquires legal title to the product or only an entitlement to use it (for example, under a lease, hire-purchase, sharing agreement, or other arrangement):

- (e) whether the supplier and recipient are in the same place at the same time;
 - (f) how the therapeutic product is supplied.
- (5) A person (the **supplier**) supplies a therapeutic product to a particular person (the **recipient**) if the supplier supplies the product—
- (a) to the recipient in person; or
 - (b) to a person who has lawful authority to receive the product for the recipient.
- (6) If a patient is an animal, a reference to supplying a therapeutic product to the patient is a reference to supplying it to an owner or a carer of the animal.

43 Meanings of wholesale supply and non-wholesale supply

- (1) There are 2 kinds of supply of therapeutic products—wholesale and non-wholesale.
- (2) The supply of a medicine, medical device, or type-4 product is **wholesale supply** if the product is supplied in circumstances in which it would be reasonable for the supplier to believe that the recipient is obtaining the product for 1 or more of the following purposes:
- (a) to supply it to other persons in the course of the recipient's business;
 - (b) to administer it, or use it on patients, in the course of the recipient's business;
 - (c) to use it in a scientific, educational, or commercial laboratory;
 - (d) to use it in a manufacturing or trade process.
- (3) Any supply of a medicine, medical device, or type-4 product that is not wholesale supply (for example, retail sale or supply to patients) is **non-wholesale supply**.
- (4) In relation to an AMI, any supply of the product is **wholesale supply**.

44 Meanings of supply chain activity and person in the supply chain

- (1) Each of the following is a **supply chain activity**:
- (a) a controlled activity;
 - (b) doing any of the following in the course of business in circumstances that do not constitute carrying on a controlled activity:
 - (i) importing a therapeutic product;
 - (ii) supplying a therapeutic product;
 - (iii) administering a medicine;
 - (iv) using a medical device or type-4 product on a person or an animal;
 - (v) taking a therapeutic product overseas;

- (vi) being in possession of a therapeutic product.
- (2) A person who carries on a supply chain activity is a **person in the supply chain**.

45 Meaning of take overseas

To **take overseas** a therapeutic product means to take the product from a place in New Zealand to a place outside New Zealand in circumstances that do not constitute supply of the product.

46 Meanings of use and prepare for use

- (1) To **use** a medical device or type-4 product means to do either or both of the following:
 - (a) prepare the device or product for use:
 - (b) use the device or product for a therapeutic purpose in, on, or in relation to, a person or animal.
- (2) In relation to a medical device or type-4 product, to **prepare for use** includes the following:
 - (a) to assemble the device or product:
 - (b) to calibrate or adjust the device or product before putting it into service or for a particular patient.

Subpart 4—Miscellaneous

47 Fit and proper person

- (1) In determining whether a person (**person A**) is a fit and proper person for any purpose under this Act, the Regulator must have regard to the following:
 - (a) any conviction of person A for an offence in New Zealand or another country:
 - (b) if person A holds or has held a licence, permit, approval, registration, exemption, or other authorisation under a relevant law (an **authority**)—
 - (i) any suspension or revocation of the authority:
 - (ii) any enforcement or disciplinary action taken against person A in relation to the authority:
 - (iii) any disqualification from holding the authority or any other authority under the relevant law:
 - (iv) any contravention by person A of—
 - (A) the terms and conditions of the authority; or
 - (B) a provision of a relevant law that applied to person A as the holder of the authority:

- (c) whether there are other grounds for believing that person A is likely in future to contravene a provision of this Act:
 - (d) whether person A is or has been—
 - (i) bankrupt; or
 - (ii) subject to an insolvency event (as defined in section 6(4) of the Financial Markets Conduct Act 2013) or to an equivalent event under a law of another country:
 - (e) whether person A is otherwise of good character:
 - (f) any other matters that the Regulator considers relevant.
- (2) In **subsection (1)(a) to (e)**, a reference to person A includes a reference to each person—
- (a) who is or has been a senior manager of person A; or
 - (b) of whom person A is or has been a senior manager.
- (3) In this section, **relevant law** means any of the following Acts (or regulations made under them)—
- (a) this Act:
 - (b) the Agricultural Compounds and Veterinary Medicines Act 1997:
 - (c) the Biosecurity Act 1993:
 - (d) the Customs and Excise Act 2018:
 - (e) the Food Act 2014:
 - (f) the Hazardous Substances and New Organisms Act 1996:
 - (g) the Health Practitioners Competence Assurance Act 2003:
 - (h) the Human Assisted Reproductive Technology Act 2004:
 - (i) the Human Tissue Act 2008:
 - (j) the Medicines Act 1981 (repealed):
 - (k) the Misuse of Drugs Act 1975:
 - (l) the Psychoactive Substances Act 2013:
 - (m) the Radiation Safety Act 2016:
 - (n) a law of the Commonwealth of Australia or a State or Territory of Australia that corresponds to all or part of this Act.

48 Meaning of senior manager

A person (**person A**) is a **senior manager** of another person (**person B**) if—

- (a) person A is a director of person B (as defined in section 6(1) of the Financial Markets Conduct Act 2013); or
- (b) person A occupies a position in relation to person B that allows person A to exercise significant influence over the management or administration

of person B (for example, a chief executive or a chief financial officer);
or

- (c) person A is otherwise able, whether directly or through 1 or more interposed entities, to exercise significant influence over the management or administration of person B.

49 Meanings of work and worker

- (1) To **work** in a business or for a person means to carry out work in any capacity in the business or for the person, including work as any of the following:
 - (a) an employee:
 - (b) a contractor or subcontractor:
 - (c) an employee of a contractor or subcontractor:
 - (d) an employee of a labour hire company who has been assigned to work in the business or for the person:
 - (e) an apprentice, a trainee, or a student undertaking practical training.
- (2) A **worker** means—
 - (a) in relation to a business, a person who works in the business:
 - (b) in relation to a licence or permit, a person who works for the licensee or permit holder or otherwise in the business to which the licence or permit relates:
 - (c) in relation to a health practitioner or a veterinarian, a person who works for, or in the same business as, the health practitioner or veterinarian.

50 Examples

An example in this Act has the following status:

- (a) the example is only illustrative of the provision to which it relates and does not limit the provision; and
- (b) if the example and the provision to which it relates are inconsistent, the provision prevails.

Part 3

Dealing with therapeutic products

Subpart 1—Product approval requirements

51 Product approval required to import or supply medicine, medical device, or type-4 product

- (1) A person must not import or supply a medicine, medical device, or type-4 product unless—
 - (a) the product is—

- (i) an approved product; or
 - (ii) an approval-exempt product; or
 - (b) the person is authorised by a licence, permit, or provision of **subpart 3 of Part 3** to import or supply the product without it being approved.
- (2) If a person contravenes **subsection (1)** in circumstances that are not infringement circumstances,—
- (a) if they do so wilfully, they commit a level A1 offence; or
 - (b) if they do so recklessly, they commit a level A2 offence; or
 - (c) otherwise, they commit a level A3 offence.
- (3) A person who commits an offence under **subsection (2)** is liable on conviction to the appropriate penalty set out in **section 233**.
- (4) A person who contravenes **subsection (1)** in infringement circumstances commits an infringement offence and is liable to an infringement fee or a fine as set out in **section 251**.

52 Sponsor’s consent required to import approved product

- (1) A person must not import an approved product unless they—
- (a) are the product’s sponsor; or
 - (b) import the product with the written consent of the sponsor; or
 - (c) are authorised by a licence, permit, or provision of **subpart 3 of Part 3** to import the product without the sponsor’s consent.
- (2) If a person contravenes **subsection (1)** in circumstances that are not infringement circumstances,—
- (a) if they do so wilfully, they commit a level A1 offence; or
 - (b) if they do so recklessly, they commit a level A2 offence; or
 - (c) otherwise, they commit a level A3 offence.
- (3) A person who commits an offence under **subsection (2)** is liable on conviction to the appropriate penalty set out in **section 233**.
- (4) A person who contravenes **subsection (1)** in infringement circumstances commits an infringement offence and is liable to an infringement fee or a fine as set out in **section 251**.

Subpart 2—Controlled activities and supply chain activities

53 Authorisation required for controlled activity

- (1) A person must not carry on a controlled activity unless they are authorised to do so by a licence, permit, or provision of **subpart 3 of Part 3**.
- (2) Each of the following is a **controlled activity**:

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- (a) manufacturing a therapeutic product (which, for medicines, includes compounding and dispensing):
 - (b) the wholesale supply of—
 - (i) a medical device:
 - (ii) a category 1, 2, or 3 medicine:
 - (iii) a category 1 AMI:
 - (iv) a type-4 product:
 - (c) the non-wholesale supply of—
 - (i) a category 1 medicine:
 - (ii) a category 2 or 3 medicine in the course of business:
 - (iii) a supply-restricted device contrary to supply restrictions:
 - (iv) a type-4 product:
 - (d) prescribing a medicine:
 - (e) issuing a special clinical needs supply authority for a therapeutic product:
 - (f) administering a category 1 medicine:
 - (g) possessing—
 - (i) a category 1 medicine:
 - (ii) a category 1 AMI:
 - (h) taking overseas in the course of business:
 - (i) a category 1, 2, or 3 medicine:
 - (ii) a category 1 AMI:
 - (i) issuing a standing order in relation to a medicine:
 - (j) using a use-restricted device on a person contrary to use restrictions:
 - (k) using a type-4 product on a person or animal in the course of business:
 - (l) conducting a clinical trial of a therapeutic product:
 - (m) carrying on a pharmacy business.
- (3) If a person contravenes **subsection (1)** in circumstances that are not infringement circumstances,—
- (a) if they do so wilfully, they commit a level A1 offence; or
 - (b) if they do so recklessly, they commit a level A2 offence; or
 - (c) otherwise, they commit a level A3 offence.
- (4) A person who commits an offence under **subsection (3)** is liable on conviction to the appropriate penalty set out in **section 233**.

- (5) A person who contravenes **subsection (1)** in infringement circumstances commits an infringement offence and is liable to an infringement fee or a fine as set out in **section 251**.

54 Non-wholesale supply of category 1 medicine: prescription required

- (1) A person must not supply a category 1 medicine by non-wholesale supply unless they—
- (a) supply it in accordance with a complying prescription to the patient for whom it is prescribed; or
 - (b) are an authorised prescriber for the medicine; or
 - (c) are authorised by a licence, permit, or provision of **subpart 3 of Part 3** to supply it without a complying prescription.
- (2) If a person contravenes **subsection (1)**,—
- (a) if they do so wilfully, they commit a level A1 offence; or
 - (b) if they do so recklessly, they commit a level A2 offence; or
 - (c) otherwise, they commit a level A3 offence.
- (3) A person who commits an offence under **subsection (2)** is liable on conviction to the appropriate penalty set out in **section 233**.

55 Persons in supply chain must comply with regulations

- (1) A person in the supply chain must comply with any requirements specified in the regulations in relation to any of the following:
- (a) if the person carries on a controlled activity, how that activity is carried on (*see* **subsection (2)**):
 - (b) product and consumer information for therapeutic products:
 - (c) packaging and labelling for therapeutic products:
 - (d) storage, handling, security, transport, and disposal of therapeutic products:
 - (e) tracing and recall of therapeutic products (*see* **subsection (4)**):
 - (f) record keeping, auditing, and giving information to the Regulator:
 - (g) in relation to the issuing of a standing order or special clinical needs supply authority, ongoing monitoring by the issuer of conduct authorised by the order or authority (*see* **subsection (5)**).
- (2) Regulations specifying how a controlled activity is carried on may (without limitation) relate to any of the following:
- (a) when, where, and how the activity is carried on:
 - (b) the premises, equipment, and materials used in carrying on the activity:
 - (c) the processes, practices, methods, and procedures used in carrying on the activity:

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- (d) quality control and assurance in relation to the carrying on of the activity;
 - (e) the qualification, training, and competency of persons involved in carrying on the activity.
- (3) In relation to supplying, prescribing, or administering a medicine, or the supply or use of a medical device or type-4 product, regulations for the purposes of **subsection (2)(a)** may (without limitation) relate to any of the following:
- (a) the circumstances in which a therapeutic product may, or must not, be supplied, prescribed, administered, and used;
 - (b) the persons by whom a therapeutic product may, or must not, be supplied, prescribed, administered, and used;
 - (c) the supply, administration, and use of damaged therapeutic products;
 - (d) the supply, administration, and use of therapeutic product after their expiry date.
- (4) Regulations specifying tracing and recall requirements may (without limitation) relate to any of the following:
- (a) having in place procedures for tracing and recalling therapeutic products;
 - (b) conducting simulations or other tests of those procedures;
 - (c) implementing those procedures to trace or recall therapeutic products;
 - (d) responding to recall orders;
 - (e) how recalled products are dealt with.
- (5) Regulations specifying ongoing monitoring requirements for standing orders or special clinical needs supply authorities may (without limitation) relate to monitoring and reviewing any of the following:
- (a) the need for the standing order or special clinical needs supply authority;
 - (b) the appropriateness of the terms of the order or authority;
 - (c) the conduct of persons exercising authority under the order or authority.
- (6) If a person in the supply chain contravenes **subsection (1)** in circumstances that are not infringement circumstances,—
- (a) if they do so wilfully, they commit a level A1 offence; or
 - (b) if they do so recklessly, they commit a level A2 offence; or
 - (c) otherwise, they commit a level A3 offence.
- (7) A person who commits an offence under **subsection (6)** is liable on conviction to the appropriate penalty set out in **section 233**.
- (8) A person in the supply chain who contravenes **subsection (1)** in infringement circumstances commits an infringement offence and is liable to an infringement fee or a fine as set out in **section 251**.

Subpart 3—Authorisations

56 Effect of this subpart

- (1) The provisions of this subpart authorise persons to do things for the purposes of particular provisions of **subparts 1 and 2**.
- (2) A person who is authorised for the purposes of a particular provision is still required to comply with all other provisions of **subparts 1 and 2** that are applicable to them. This includes complying with the regulations made for the purposes of **section 55**.

57 Pharmacists: approved and approval-exempt medicines*Dispensing*

- (1) For the purposes of **section 53(1) and (2)(a)**, a pharmacist may dispense an approved or approval-exempt medicine if—
 - (a) the pharmacist complies with the licence requirements in **subsection (3)**; and
 - (b) if it is a category 1 medicine, the medicine is dispensed in accordance with a complying prescription.

Non-wholesale supply of category 1, 2, or 3 medicine

- (2) For the purposes of **section 53(1) and (2)(c)(i) and (ii)**, a pharmacist may supply an approved or approval-exempt category 1, 2, or 3 medicine by non-wholesale supply if—
 - (a) the pharmacist complies with the licence requirements in **subsection (3)**; and
 - (b) if it is a category 2 medicine, the medicine is supplied—
 - (i) in accordance with a complying prescription; or
 - (ii) after the pharmacist has determined that the medicine is appropriate for the patient.
- (3) The **licence requirements** for a pharmacist, in relation to a controlled activity, are that the pharmacist—
 - (a) is working in a licensed pharmacy business; and
 - (b) carries on the activity at a place—
 - (i) specified in the licence as one at which the activity may be carried on; or
 - (ii) at which the regulations permit the activity to be carried on; and
 - (c) otherwise carries on the activity in accordance with the terms and conditions of the licence.

58 Pharmacists: unapproved products*Compounding*

- (1) For the purposes of **section 53(1) and (2)(a)**, a pharmacist may compound an unapproved medicine if—
- (a) the pharmacist complies with the licence requirements in **section 57(3)**; and
 - (b) if it is a category 1 medicine, the medicine is compounded in accordance with a complying prescription.

Non-wholesale supply of category 1, 2, or 3 medicine and dispensing

- (2) For the purposes of **sections 51 and 53**, a pharmacist may carry on a controlled activity referred to in **section 57** in relation to an unapproved medicine if—
- (a) the pharmacist would be authorised by **section 57** to do so if the medicine were an approved medicine; and
 - (b) either—
 - (i) there is a complying special clinical needs supply authority for the patient for that medicine; or
 - (ii) the medicine was lawfully compounded for the patient.

Non-wholesale supply of category 4 medicine

- (3) For the purposes of **section 51**, a pharmacist may supply an unapproved category 4 medicine by non-wholesale supply if—
- (a) the pharmacist complies with the licence requirements in **section 57(3)**; and
 - (b) either—
 - (i) there is a complying special clinical needs supply authority for the patient for that medicine; or
 - (ii) the medicine was lawfully compounded for the patient.

Non-wholesale supply of medical device

- (4) For the purposes of **section 51**, a pharmacist may supply an unapproved medical device by non-wholesale supply if—
- (a) the pharmacist complies with the licence requirements in **section 57(3)**; and
 - (b) there is a complying special clinical needs supply authority for the patient for that device.

Importing

- (5) For the purposes of **section 51**, a pharmacist may import an unapproved medicine or medical device if—

- (a) the pharmacist complies with the licence requirements in **section 57(3)**; and
- (b) the medicine or device is imported for the purposes of it being supplied to a particular patient; and
- (c) there is a complying special clinical needs supply authority for the patient for the medicine or device; and
- (d) the medicine or device is imported at the request of the person who issued the special clinical needs supply authority.

59 Pharmacists: wholesale supply (approved, approval-exempt, and unapproved products)

- (1) For the purposes of **sections 51 and 53(1) and (2)(b)**, a pharmacist may supply a medicine or medical device by wholesale supply if—
 - (a) the pharmacist complies with the licence requirements in **section 57(3)**; and
 - (b) the regulations permit the medicine or device to be supplied under this section; and
 - (c) the pharmacist complies with any requirements specified in the regulations in relation to that supply.
- (2) For the purposes of **sections 51 and 53(1) and (2)(a)**, a pharmacist may take a step in the manufacture of a medicine if—
 - (a) the pharmacist is authorised under **subsection (1)** to supply the medicine by wholesale supply; and
 - (b) taking the step is reasonably necessary to enable the pharmacist to supply the medicine; and
 - (c) the regulations permit the pharmacist to take the step; and
 - (d) the pharmacist complies with the licence requirements in **section 57(3)**; and
 - (e) the pharmacist complies with any requirements specified in the regulations in relation to taking the step.

60 Qualified pharmacy workers

- (1) For the purposes of **sections 51 and 53**, a pharmacy worker may carry on an activity that **section 57, 58, or 59** authorises a pharmacist to carry on if the worker—
 - (a) is qualified to carry on the activity; and
 - (b) carries on the activity in a way that **section 57, 58, or 59** authorises a pharmacist to carry on the activity; and
 - (c) carries on the activity under the following level of supervision, or any lower level of supervision permitted by the rules,—

- (i) for the non-wholesale supply of a category 3 medicine, the general supervision of a pharmacist (**pharmacist A**); or
 - (ii) for any other activity, the direct supervision of a pharmacist (**pharmacist B**).
- (2) However, if pharmacist A or B's authority to carry on the activity is subject to any limitations, the pharmacy worker is subject to the same limitations.
- (3) To avoid doubt, **section 57(2)(b)(ii)** as applied by **subsection (1)(b)** of this section requires a determination of the appropriateness of the medicine for the patient to be made by a pharmacist, not by the pharmacy worker.

61 Health practitioners: approved and approval-exempt medicines

Non-wholesale supply of category 1 or 2 medicine

- (1) For the purposes of **section 53(1) and (2)(c)(i) and (ii)**, a health practitioner may supply an approved or approval-exempt category 1 or 2 medicine by non-wholesale supply if—
 - (a) they are a health practitioner prescriber for that medicine; and
 - (b) the medicine is supplied—
 - (i) to a patient of the practitioner; or
 - (ii) for a patient of, and at the request of, another health practitioner prescriber for the medicine; and
 - (c) the patient is in New Zealand or is ordinarily resident in New Zealand.

Non-wholesale supply of category 3 medicine

- (2) For the purposes of **section 53(1) and (2)(c)(ii)**, a health practitioner may supply an approved or approval-exempt category 3 medicine by non-wholesale supply if—
 - (a) the medicine is relevant to a health service that forms part of the practitioner's scope of practice; and
 - (b) the medicine is supplied—
 - (i) to a patient of the practitioner; or
 - (ii) for a patient of, and at the request of, another health practitioner; and
 - (c) the patient is in New Zealand or is ordinarily resident in New Zealand.

Prescribing medicine

- (3) For the purposes of **section 53(1) and (2)(d)**, a health practitioner may prescribe an approved or approval-exempt medicine if—
 - (a) they are a health practitioner prescriber for that medicine; and
 - (b) the medicine is prescribed—
 - (i) for a patient of the practitioner; or

- (ii) for a patient of, and at the request of, another health practitioner prescriber for the medicine; and
- (c) the patient is in New Zealand or is ordinarily resident in New Zealand; and
- (d) any requirements for complying prescriptions specified in the regulations referred to in **section 38(2)** are complied with.

Administering category 1 medicine

- (4) For the purposes of **section 53(1) and (2)(f)**, a health practitioner may administer an approved or approval-exempt category 1 medicine to another person if—
 - (a) they are a health practitioner prescriber for that medicine; and
 - (b) the medicine is administered—
 - (i) to a patient of the practitioner; or
 - (ii) to a patient of, and at the request of, another health practitioner prescriber for the medicine.

Dispensing

- (5) For the purposes of **section 53(1) and (2)(a)**, a health practitioner may dispense an approved or approval-exempt medicine if—
 - (a) they are a health practitioner prescriber for that medicine; and
 - (b) the medicine is dispensed—
 - (i) for a patient of the practitioner; or
 - (ii) for a patient of, and at the request of, another health practitioner prescriber for the medicine; and
 - (c) the patient is in New Zealand or is ordinarily resident in New Zealand.

Issuing standing order

- (6) For the purposes of **section 53(1) and (2)(i)**, a health practitioner may issue a standing order for 1 or more approved or approval-exempt medicines if—
 - (a) they are a health practitioner prescriber for every medicine to which the standing order applies; and
 - (b) their scope of practice includes the issuing of standing orders for those medicines; and
 - (c) every person authorised by the order is a person engaged in the delivery of health services (as defined in section 2 of the Health and Disability Commissioner Act 1994); and
 - (d) everything that the standing order authorises a person to do is something that the practitioner could lawfully do; and
 - (e) any requirements for standing orders specified in the regulations referred to in **section 40(2)** are complied with.

62 Health practitioners: unapproved products

Non-wholesale supply of category 1, 2, or 3 medicine, prescribing, administering, dispensing

- (1) For the purposes of **sections 51 and 53**, a health practitioner may carry on a controlled activity referred to in **section 61(1) to (5)** in relation to an unapproved medicine if—
 - (a) they would be authorised by **section 61** to do so if the medicine were an approved medicine; and
 - (b) either—
 - (i) there is a complying special clinical needs supply authority for the patient for that medicine; or
 - (ii) the medicine,—
 - (A) in the case of supplying, administering, or dispensing, was lawfully compounded for the patient; or
 - (B) in the case of prescribing, will be compounded for the patient.

Non-wholesale supply of category 4 medicine

- (2) For the purposes of **section 51**, a health practitioner may supply an unapproved category 4 medicine by non-wholesale supply if—
 - (a) the practitioner is a health practitioner prescriber for that medicine; and
 - (b) the medicine is supplied—
 - (i) to a patient of the practitioner; or
 - (ii) for a patient of, and at the request of, another health practitioner prescriber for the medicine; and
 - (c) the patient is in New Zealand or is ordinarily resident in New Zealand; and
 - (d) either—
 - (i) there is a complying special clinical needs supply authority for the patient for that medicine or device; or
 - (ii) the medicine was lawfully compounded for the patient.

Non-wholesale supply of medical device

- (3) For the purposes of **section 51**, a health practitioner may supply an unapproved medical device by non-wholesale supply if—
 - (a) the device is relevant to a health service that forms part of the practitioner's scope of practice; and
 - (b) the device is supplied—
 - (i) to a patient of the practitioner; or

- (ii) for a patient of, and at the request of, another health practitioner whose scope of practice includes the same health service; and
- (c) the patient is in New Zealand or is ordinarily resident in New Zealand; and
- (d) there is a complying special clinical needs supply authority for the patient for that device.

63 Health practitioners: wholesale supply (approved, approval-exempt, and unapproved products)

For the purposes of **sections 51 and 53(1) and (2)(b)**, a health practitioner may supply a medicine or medical device by wholesale supply if—

- (a) the regulations permit the medicine or device to be supplied under this section; and
- (b) for a medicine, the health practitioner supplying it and the person to whom it is supplied are both health practitioner prescribers for the medicine; and
- (c) for a medical device, it is supplied to a health practitioner; and
- (d) the health practitioner complies with any requirements specified in the regulations in relation to that supply.

64 Health practitioners: special clinical needs supply authority

(1) For the purposes of **section 53(1) and (2)(e)**, a health practitioner may issue a special clinical needs supply authority for an unapproved medicine or medical device for a person if—

- (a) the person is a patient of the practitioner; and
- (b) either—
 - (i) for a medicine, the practitioner is a health practitioner prescriber for the unapproved medicine; or
 - (ii) for a medical device, the device is relevant to a health service that forms part of the practitioner’s scope of practice; and
- (c) the regulations permit the special clinical needs supply authority to be issued; and
- (d) the practitioner is satisfied that the patient has a clinical need for a medicine or device; and
- (e) the practitioner is satisfied that—
 - (i) no approved or approval-exempt product is available to meet that need; or
 - (ii) if 1 or more approved or approval-exempt products are available to meet that need, there are special clinical reasons why none of them are suitable for the patient; and

- (f) any other criteria specified in the regulations are met.
- (2) For the purposes of **section 51**, a health practitioner who issues a complying special clinical needs supply authority for an unapproved medicine or medical device for a patient may import the medicine or device for the patient.
- (3) Regulations for the purposes of **subsection (1)(c)** may (without limitation) specify:
 - (a) classes of health practitioners who may, or may not, issue a special clinical needs supply authority;
 - (b) the circumstances in which health practitioners may, or may not, issue a special clinical needs supply authority;
 - (c) the medicines or medical devices for which health practitioners may, or may not, issue a special clinical needs supply authority.

65 Health practitioner's staff: non-wholesale supply of category 3 medicine

- (1) For the purposes of **section 53(1) and (2)(c)(ii)**, a person who works for a health practitioner may supply an approved or approval-exempt category 3 medicine by non-wholesale supply if—
 - (a) the health practitioner is authorised by **section 61** to supply the medicine; and
 - (b) the medicine is supplied to a patient of the health practitioner; and
 - (c) the worker supplies the medicine under the general supervision of the health practitioner.
- (2) However, if the health practitioner's authority to supply the medicine is subject to any limitations, the worker is subject to the same limitations.

66 Veterinarians: approved medicines

Non-wholesale supply of category 1, 2, or 3 medicine

- (1) For the purposes of **section 53(1) and (2)(c)(i) and (ii)**, a veterinarian may supply an approved or approval-exempt category 1, 2, or 3 medicine by non-wholesale supply if—
 - (a) the medicine is supplied—
 - (i) to a patient of the veterinarian; or
 - (ii) for a patient of, and at the request of, another veterinarian; and
 - (b) the patient is in New Zealand or is ordinarily resident in New Zealand.

Prescribing medicine

- (2) For the purposes of **section 53(1) and (2)(d)**, a veterinarian may prescribe an approved or approval-exempt medicine if—
 - (a) the medicine is prescribed—
 - (i) for a patient of the veterinarian; or

- (ii) for a patient of, and at the request of, another veterinarian; and
- (b) the patient is in New Zealand or is ordinarily resident in New Zealand; and
- (c) any requirements for complying prescriptions specified in the regulations referred to in **section 38(2)** are complied with.

Administering category 1 medicine

- (3) For the purposes of **section 53(1) and (2)(f)**, a veterinarian may administer an approved or approval-exempt category 1 medicine to an animal if it is administered—
 - (a) to a patient of the veterinarian; or
 - (b) to a patient of, and at the request of, another veterinarian.

Dispensing

- (4) For the purposes of **section 53(1) and (2)(a)**, a veterinarian may dispense an approved or approval-exempt medicine if—
 - (a) it is dispensed—
 - (i) for a patient of the veterinarian; or
 - (ii) for a patient of, and at the request of, another veterinarian; and
 - (b) the patient is in New Zealand or is ordinarily resident in New Zealand.

67 Veterinarians: unapproved products

Non-wholesale supply of category 1, 2, or 3 medicine, prescribing, administering, dispensing

- (1) For the purposes of **sections 51 and 53**, a veterinarian may carry on a controlled activity referred to in **section 66** in relation to an unapproved medicine if—
 - (a) they would be authorised by **section 66** to do so if the medicine were an approved medicine; and
 - (b) there is a complying special clinical needs supply authority for the patient for that medicine.

Non-wholesale supply of category 4 medicine or medical device

- (2) For the purposes of **section 51**, a veterinarian may supply an unapproved category 4 medicine or an unapproved medical device by non-wholesale supply if—
 - (a) the medicine or device is supplied—
 - (i) to a patient of the veterinarian; or
 - (ii) for a patient of, and at the request of, another veterinarian; and
 - (b) the patient is in New Zealand or is ordinarily resident in New Zealand; and

- (c) there is a complying special clinical needs supply authority for the patient for that medicine or device.

68 Veterinarians: wholesale supply (approved, approval-exempt, and unapproved products)

For the purposes of **sections 51 and 53(1) and (2)(b)**, a veterinarian may supply a medicine or medical device by wholesale supply if—

- (a) the regulations permit the medicine or device to be supplied under this section; and
- (b) the medicine or device is supplied to another veterinarian; and
- (c) the veterinarian complies with any requirements specified in the regulations in relation to that supply.

69 Veterinarians: special clinical needs supply authority

- (1) For the purposes of **section 53(1) and (2)(e)**, a veterinarian may issue a special clinical needs supply authority for an unapproved medicine or device for an animal if—
 - (a) the animal is a patient of the veterinarian; and
 - (b) the veterinarian is satisfied that—
 - (i) the patient has a clinical need for medicine; and
 - (ii) the use of the unapproved medicine or device to meet that need is clinically appropriate; and
 - (c) the regulations permit the special clinical needs supply authority to be issued; and
 - (d) any other criteria specified in the regulations are met.
- (2) For the purposes of **section 51**, a veterinarian who issues a complying special clinical needs supply authority for an unapproved medicine for a patient may import the medicine for the patient.
- (3) Regulations for the purposes of **subsection (1)(c)** may (without limitation) specify:
 - (a) classes of veterinarian who may, or may not, issue a special clinical needs supply authority;
 - (b) the circumstances in which veterinarians may, or may not, issue a special clinical needs supply authority;
 - (c) the medicines or medical devices for which veterinarian may, or may not, issue a special clinical needs supply authority.

70 Veterinary staff

- (1) For the purposes of **section 53**, a person who works for a veterinarian may supply an approved or approval-exempt category 3 medicine by non-wholesale supply if—
 - (a) the veterinarian is authorised by **section 66** to supply the medicine; and
 - (b) the medicine is supplied to a patient of the veterinarian; and
 - (c) the worker supplies the medicine under the general supervision of the veterinarian.
- (2) For the purposes of **section 53**, a person who works for a veterinarian may carry on a controlled activity referred to in **section 66** (other than the supply of a category 3 medicine by non-wholesale supply) if—
 - (a) the veterinarian is authorised to carry on the activity; and
 - (b) the worker carries on the activity in a way that **section 66** authorises the veterinarian to carry on the activity; and
 - (c) the worker carries on the activity at the request of, and under the direct supervision of, the veterinarian.
- (3) However, if the veterinarian's authority to carry on the activity is subject to any limitations, the worker is subject to the same limitations.

71 Person authorised by standing order

For the purposes of **sections 53(1) and (2)(c)(i) and (ii), and (f), and 54**, a person may do any of the following if authorised to do so by a standing order:

- (a) supply an approved or approval-exempt category 1, 2, or 3 medicine by non-wholesale supply;
- (b) supply an approved or approval-exempt category 1 medicine without a complying prescription;
- (c) administer an approved or approval-exempt category 1 medicine.

72 Downstream supply or administration of medicine to patient

- (1) **Subsection (2)** applies if an approved or approval-exempt category 1, 2, or 3 medicine is lawfully supplied by non-wholesale supply in New Zealand to a person (**person A**) who is not the patient for whom the medicine is intended.
- (2) For the purposes of **sections 53(1) and (2)(c)(i) and (ii), and (f), and 54**, person A—
 - (a) may—
 - (i) supply the medicine to the patient; and
 - (ii) if it is a category 1 medicine, do so without a complying prescription; or

- (b) may, if it is a category 1 medicine, administer it to the patient in accordance with the directions of the authorised prescriber who supplied or prescribed it.
- (3) If an unapproved medicine is lawfully supplied by non-wholesale supply in New Zealand to a person (**person B**) who is not the patient for whom the medicine is intended, for the purposes of **sections 51 and 54**, person B may—
 - (a) supply the medicine to the patient; and
 - (b) if it is a category 1 medicine, do so without a complying prescription.

73 Possession of category 1 medicine

For the purposes of **section 53(1) and (2)(g)(i)**, a person may possess a category 1 medicine if—

- (a) the medicine was lawfully supplied to the person by non-wholesale supply; or
- (b) the person—
 - (i) is authorised by a licence, permit, or provision of this Act to carry on a controlled activity in relation to the medicine; and
 - (ii) has possession of the medicine incidental to carrying on that activity.

74 Possession of category 1 AMI

For the purposes of **section 53(1) and (2)(g)(ii)**, a person may possess a category 1 AMI if—

- (a) the AMI was lawfully supplied to the person; or
- (b) the person—
 - (i) is authorised by a licence, permit, or provision of this Act to carry on a controlled activity in relation to the AMI; and
 - (ii) has possession of the AMI incidental to carrying on that activity.

75 Manufacture of custom-made devices

For the purposes of **section 53(1) and (2)(a)**, a person may manufacture a medical device if—

- (a) they meet the criteria specified in the regulations for a person who may manufacture the device; and
- (b) the device is—
 - (i) manufactured at the request of a health practitioner for a particular identified patient of that practitioner; and
 - (ii) custom-made to meet the needs of that patient; and
- (c) the person complies with any requirements specified in the regulations.

76 Patient or carer importing medicine for personal use

- (1) For the purposes of **section 51 or 52**, an individual (**person A**) may do either of the following if they comply with the personal use import conditions:
 - (a) import a medicine without it being approved; or
 - (b) import an approved medicine without the sponsor's consent.
- (2) However, this section does not apply to a medicine specified in the regulations as one to which this section does not apply.
- (3) The **personal use import conditions** are that—
 - (a) person A acquired the medicine lawfully; and
 - (b) the patient for whom the medicine is intended is—
 - (i) person A; or
 - (ii) another person or an animal for whom person A is a carer; and
 - (c) in importing the medicine, person A is not acting in the course of a business; and
 - (d) either—
 - (i) the luggage conditions in **subsection (4)** are complied with; or
 - (ii) the delivery conditions in **subsection (5)** are complied with.
- (4) The **luggage conditions** are that—
 - (a) person A brings the medicine into New Zealand with them in their personal luggage; and
 - (b) if person A is not the patient, the patient is travelling with person A; and
 - (c) the amount of the medicine imported by person A at one time does not exceed—
 - (i) if the medicine was prescribed by an authorised prescriber or an overseas health professional, the amount so prescribed; or
 - (ii) otherwise, 3 months' standard supply.
- (5) The **delivery conditions** are that—
 - (a) the medicine is a category 2, 3, or 4 medicine; and
 - (b) the amount of the medicine imported by person A at one time does not exceed 3 months' standard supply; and
 - (c) the amount of the medicine imported for the patient (regardless of who imports it or how it is imported) does not exceed 15 months' standard supply in any 12-month period.
- (6) If a medicine obtained overseas is imported in reliance on this section, **sections 72 and 73** apply as if—
 - (a) the medicine had been supplied in New Zealand; and

- (b) **section 72(2)(b)** referred to the directions of the overseas health professional who supplied or prescribed the medicine (or if it wasn't supplied or prescribed by a health professional, to the responsible manufacturer's instructions).
- (7) A reference to a number of months' **standard supply** of a medicine means the amount of the medicine that a notional average patient with the same condition would require for that number of months calculated on the basis of the recommended daily dose specified by the medicine's responsible manufacturer.

77 Patient or carer importing medical device for personal use

- (1) For the purposes of **section 51 or 52**, an individual (**person A**) may do either of the following if they comply with the personal use import conditions:
 - (a) import a medical device without it being approved; or
 - (b) import an approved device without the sponsor's consent.
- (2) However, this section does not apply to a medical device that is specified in the regulations as one to which this section does not apply.
- (3) The **personal use import conditions** for a device are that—
 - (a) the device is imported for the purpose of its use on—
 - (i) person A; or
 - (ii) another person or an animal for whom person A is a carer; and
 - (b) in importing the device, person A is not acting in the course of a business.

78 Authorisation for unapproved product stock in supply chain

- (1) This section applies if—
 - (a) one of the following occurs:
 - (i) a therapeutic product's (**product A**) approval is cancelled (by the Regulator under **section 109** or a court under **section 236**); or
 - (ii) a therapeutic product's (**product A**) approval lapses under **section 104**; or
 - (iii) a major change is made to an approved product and the changed product (**product A**) is released into the supply chain without being approved (*see section 100*); and
 - (b) a use of current stock notice is in force for product A.
- (2) For the purposes of **sections 51 to 55**, a person may carry on an activity referred to in any of those sections in relation to product A if—
 - (a) the person would be authorised to carry on the activity in relation to product A if it were an approved product; and
 - (b) the particular product in relation to which the person carries on the activity is current stock.

- (3) However, this section does not apply to the sponsor of product A (in their capacity as sponsor or in any other capacity).
 - (4) If a person is authorised by this section to carry on an activity in relation to product A,—
 - (a) the authorisation is subject to the same terms and conditions as the person's authorisation referred to in **subsection (2)(a)**; and
 - (b) this Act applies to the person as if product A were an approved product.
 - (5) A **use of current stock notice** is a Regulator's notice identifying particular stock of a therapeutic product (**current stock**) as stock to which this section applies.
 - (6) Stock identified in a use of current stock notice—
 - (a) must exist at the time the notice is made; and
 - (b) may be identified in any way the Regulator considers appropriate.
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Example

Company M is the sponsor for product A and also imports and wholesales the product. Product A's approval is cancelled but the Regulator issues a use of current stock notice for stock already in the supply chain. This allows health retailers, health practitioners, etc to continue to sell and use product A. But because Company M is the sponsor, it could not rely on this section to import or wholesale more stock.

There are other ways in which Company M could be authorised to import or wholesale more stock (such as a permit), or it could seek to get the product approved again.

79 Regulations may grant authorisations

- (1) For the purposes of **sections 51 to 55**, a person may do anything that would otherwise contravene those sections if they are authorised to do so by the regulations.
- (2) The regulations may authorise a person to do anything that would otherwise contravene any of **sections 51 to 55**.

80 Vending machines for medicine to be expressly authorised

A licence, permit, or provision of this Act that authorises a person to supply a medicine does not authorise supply by vending machine unless the licence, permit, or provision expressly states that it does.

Subpart 4—Other offences

Prohibited products

81 Prohibited products

- (1) A person must not import, manufacture, supply, administer or use on a patient, or be in possession of, a prohibited product unless authorised to do so by a permit.
- (2) The regulations may specify criteria for granting a permit relating to a prohibited product for the purposes of **section 135(e)**.
- (3) If a person contravenes **subsection (1)**,—
 - (a) if they do so wilfully, they commit a level A1 offence; or
 - (b) if they do so recklessly, they commit a level A2 offence; or
 - (c) otherwise, they commit a level A3 offence.
- (4) A person who commits an offence under **subsection (3)** is liable on conviction to the appropriate penalty set out in **section 233**.

Advertising

82 Meaning of advertisement and related terms

- (1) An **advertisement** for a therapeutic product means a communication made to the public or a section of the public for the purpose of promoting the product.
- (2) A **communication** means a communication made in any way, whether made by an individual in person, using a physical object, or by means of any kind of audio, visual, electronic, or other method of communication.
- (3) However, the following are not advertisements for a therapeutic product:
 - (a) any of the following made by the Regulator:
 - (i) a statement made under **section 161**:
 - (ii) a recall order:
 - (b) a statement, approved by the chief executive of the Ministry, that is made as part of a public health campaign:
 - (c) the pharmaceutical schedule (as defined in section 6(1) of the New Zealand Public Health and Disability Act 2000) published by the Pharmaceutical Management Agency (Pharmac) under that Act:
 - (d) a communication that a person is required to make under this Act or any other law (provided that it complies with the law that requires it to be made):
 - (e) a communication of a kind specified in the regulations.

- (4) To **distribute**, in relation to a communication, includes to make available, publish, display, circulate, broadcast, transmit, or otherwise bring to the notice of the public or a section of the public.

83 Advertising

- (1) A person must not distribute an advertisement for a therapeutic product unless,—
- (a) for a medicine, medical device, or type-4 product, the product is an approved product or an approval-exempt product; and
 - (b) the advertisement complies with the advertisement requirements in **subsection (2)**; and
 - (c) the distribution complies with any distribution requirements specified in the regulations.
- (2) The **advertisement requirements** are that an advertisement—
- (a) must contain—
 - (i) the name of the person who is promoting the product using the advertisement; and
 - (ii) any other information specified in the regulations; and
 - (b) must not contain,—
 - (i) if it is an approved product, information that is, directly or by implication, inconsistent with its approval; or
 - (ii) any misleading information; and
 - (c) must comply with any requirements specified in the regulations.
- (3) Regulations specifying advertisement or distribution requirements may (without limitation) relate to any of the following:
- (a) the content of an advertisement:
 - (b) the form of an advertisement:
 - (c) how an advertisement is distributed:
 - (d) to whom an advertisement is distributed.
- (4) If a person contravenes **subsection (1)** in circumstances that are not infringement circumstances,—
- (a) if they do so wilfully, they commit a level A1 offence; or
 - (b) if they do so recklessly, they commit a level A2 offence; or
 - (c) otherwise, they commit a level A3 offence.
- (5) A person who commits an offence under **subsection (4)** is liable on conviction to the appropriate penalty set out in **section 233**.

- (6) A person who contravenes **subsection (1)** in infringement circumstances commits an infringement offence and is liable to an infringement fee or a fine as set out in **section 251**.

Tampering

84 Meaning of tamper with and create a risk of harm

- (1) To **tamper with** a therapeutic product means—
- (a) to interfere with—
 - (i) the product itself; or
 - (ii) the product's manufacturing process; or
 - (iii) the product's performance; or
 - (iv) the product's packaging or labelling; or
 - (v) the product's product or consumer information; and
 - (b) to do so in a way that adversely affects the product's quality, safety, or efficacy or performance, or might reasonably be expected to do so.
- (2) Tampering with a therapeutic product **creates a risk of harm** if the tampering—
- (a) directly or indirectly—
 - (i) causes harm; or
 - (ii) significantly increases harm; or
 - (iii) creates a significant risk of harm; or
 - (iv) significantly increases a risk of harm; or
 - (b) might reasonably be expected to do something referred to in **paragraph (a)**.

85 Tampering with therapeutic products

- (1) A person must not—
- (a) tamper with a therapeutic product in a way that creates a risk of harm; or
 - (b) threaten to do so; or
 - (c) claim to have done so.
- (2) If a person contravenes **subsection (1)**,—
- (a) if they know that the tampering creates a risk of harm, they commit a level A1 offence; or
 - (b) if they do so recklessly as to whether the tampering creates a risk of harm, they commit a level A2 offence; or
 - (c) otherwise, they commit a level A3 offence.

- (3) A person who commits an offence under **subsection (2)** is liable on conviction to the appropriate penalty set out in **section 233**.

86 Supply of tampered-with therapeutic products

- (1) A person in the supply chain must not supply a therapeutic product that they know or suspect has been tampered with in a way that creates a risk of harm.
- (2) If a person in the supply chain contravenes **subsection (1)**,—
- (a) if they know that the product has been tampered with in a way that creates a risk of harm, they commit a level A1 offence; or
 - (b) if they do so recklessly as to whether product has been tampered with in a way that creates a risk of harm, they commit a level A2 offence; or
 - (c) otherwise, they commit a level A3 offence.
- (3) A person who commits an offence under **subsection (2)** is liable on conviction to the appropriate penalty set out in **section 233**.

87 Notifying Regulator of suspicion of tampering

- (1) A sponsor or person in the supply chain (**person A**) must notify the Regulator if they know or suspect that—
- (a) a person—
 - (i) has tampered with a therapeutic product in a way that causes a risk of harm; or
 - (ii) is proposing to do so; or
 - (b) there is a risk that a person has done so or is proposing to do so.
- (2) **Subsection (1)** applies even if—
- (a) the therapeutic product is not in person A's possession;
 - (b) the therapeutic product does not yet exist;
 - (c) person A does not know the identity of the tamperer.
- (3) A sponsor or person in the supply chain who knows of a matter referred to in **subsection (1)(a)** and wilfully contravenes **subsection (1)** commits a level A1 offence and is liable on conviction to the penalty set out in **section 233(1)**.

Misrepresentation about therapeutic products

88 Misrepresentation about therapeutic product

- (1) A person makes a **misrepresentation about a therapeutic product** if the person represents (expressly or impliedly) something to be any of the following when it is not:
- (a) a therapeutic product;
 - (b) a particular therapeutic product;

- (c) a therapeutic product with a particular characteristic:
 - (d) a therapeutic product with a particular classification or status under this Act (for example, that it is an approved product or an approval-exempt product, or that it is a particular type of product or a medicine in a particular category).
- (2) A person must not make a misrepresentation about a therapeutic product.
- (3) If a person contravenes **subsection (2)**,—
- (a) if they know that the representation is not true, they commit a level A1 offence; or
 - (b) if they are reckless as to whether the representation is true, they commit a level A2 offence; or
 - (c) otherwise, they commit a level A3 offence.
- (4) A person who commits an offence under **subsection (3)** is liable on conviction to the appropriate penalty set out in **section 233**.

Holding out

89 Holding out

- (1) A person makes a **holding out misrepresentation** if—
- (a) the person represents (expressly or impliedly) that they or another person is any of the following if that is not the case:
 - (i) a sponsor:
 - (ii) a licensee or permit holder:
 - (iii) authorised under this Act to do something:
 - (iv) lawfully able to carry on a controlled activity or other supply chain activity; and
 - (b) the person—
 - (i) knows the representation is untrue; or
 - (ii) is reckless as to whether it is true.
- (2) A person who makes a holding out misrepresentation with intent to deceive commits a level B1 offence and is liable on conviction to the penalty set out in **section 233(4)**.

Preparatory and supporting conduct

90 Agreeing or offering to carry on supply chain activity unlawfully

- (1) A person must not offer or agree to carry on a supply chain activity in circumstances in which carrying on the activity would contravene a provision of this Act.

- (2) If a person contravenes **subsection (1)** in circumstances that are not infringement circumstances,—
 - (a) if they do so wilfully, they commit a level A1 offence; or
 - (b) if they do so recklessly, they commit a level A2 offence; or
 - (c) otherwise, they commit a level A3 offence.
- (3) A person who commits an offence under **subsection (2)** is liable on conviction to the appropriate penalty set out in **section 233**.
- (4) A person contravenes **subsection (1)** in infringement circumstances commits an infringement offence and is liable to an infringement fee or a fine as set out in **section 251**.

91 Obtaining therapeutic product when supply is unlawful

- (1) A person (**person A**) must not obtain a therapeutic product from another person (**person B**) if—
 - (a) it would be unlawful under this Act for person B to supply the product to person A; and
 - (b) person A—
 - (i) knows that it would be unlawful; or
 - (ii) is reckless as to whether it would be unlawful.
- (2) If a person contravenes **subsection (1)** in circumstances that are not infringement circumstances,—
 - (a) if they do so wilfully, they commit a level A1 offence; or
 - (b) if they do so recklessly, they commit a level A2 offence; or
 - (c) otherwise, they commit a level A3 offence.
- (3) A person who commits an offence under **subsection (2)** is liable on conviction to the appropriate penalty set out in **section 233**.
- (4) A person who contravenes **subsection (1)** in infringement circumstances commits an infringement offence and is liable to an infringement fee or a fine as set out in **section 251**.

Other offences

92 Misleading information in records

- (1) A person must not—
 - (a) include misleading information in a required record; or
 - (b) alter a required record so that information in it becomes misleading information.
- (2) If a person contravenes **subsection (1)** in circumstances that are not infringement circumstances,—

- (a) if they know that the information is misleading information, they commit a level B1 offence; or
 - (b) if they are reckless as to whether the information is misleading information, they commit a level B2 offence; or
 - (c) otherwise, they commit a level B3 offence.
- (3) A person who commits an offence under **subsection (2)** is liable on conviction to the appropriate penalty set out in **section 233**.
- (4) A person who contravenes **subsection (1)** in infringement circumstances commits an infringement offence and is liable to an infringement fee or a fine as set out in **section 251**.
- (5) In this section, **required record** means a record that a person is required under this Act to make or keep.

93 Health practitioner prescriber must not hold interest in pharmacy business

- (1) A health practitioner who is a health practitioner prescriber for 1 or more medicines must not hold an interest in a pharmacy business unless authorised to do so by the pharmacy licence under which the pharmacy business is carried on.
- (2) The Regulator must not grant a pharmacy licence that authorises a health practitioner prescriber to hold an interest in a pharmacy business unless it is subject to adequate conditions.
- (3) If a health practitioner contravenes **subsection (1)**,—
- (a) if they do so wilfully, they commit a level B1 offence; or
 - (b) if they do so recklessly, they commit a level B2 offence; or
 - (c) otherwise, they commit a level B3 offence.
- (4) A health practitioner who commits an offence under **subsection (3)** is liable on conviction to the appropriate penalty set out in **section 233**.
- (5) A person **holds an interest** in a pharmacy business if they have any estate or interest in the business that affects the ownership, management, or control of the pharmacy business (whether that estate or interest is direct or indirect, and whether it is held in the person's own name, by a nominee, or by means of any device or arrangement).
- (6) However, a person does not hold an interest in a pharmacy business if—
- (a) the person is merely doing either or both of the following:
 - (i) lending money to facilitate the carrying on of the pharmacy business;
 - (ii) holding security for repayment of such a loan; and
 - (b) in doing so, the person is acting in good faith and in the ordinary course of the person's business.

- (7) If a pharmacy business is being carried on by an executor or administrator of a deceased estate under **section 151(1)**, a person does not hold an interest in the pharmacy business merely by having an interest in the deceased estate.
- (8) In this section, **adequate conditions** means the conditions the Regulator considers are sufficient to ensure that the provision of health care (including the issuing of prescriptions) by the health practitioner is not influenced by the fact that they hold an interest in the business.

Part 4

Product approval

Subpart 1—Approval of medicines, medical devices, and type-4 products

Approvals of products

94 Approval of medicines, medical devices, and type-4 products

- (1) A person may apply to the Regulator for approval of a medicine, medical device, or type-4 product.
- (2) The Regulator must evaluate the application having regard to the following:
 - (a) the criteria for product approval in **section 95**;
 - (b) whether the product, if approved, will comply with the specified product standards;
 - (c) whether the person named in the application as the proposed sponsor meets the criteria for a sponsor in **section 97**.
- (3) After evaluating the application, the Regulator must—
 - (a) grant approval of the product to the sponsor; or
 - (b) refuse to grant approval of the product.

95 Criteria for product approval

The criteria for product approval are all of the following:

- (a) the quality, safety, and efficacy or performance of the product for the purpose for which it is to be used are satisfactorily established;
- (b) the likely benefits of the product outweigh the likely risks associated with it;
- (c) any other criteria for approval that are specified in the rules.

96 Product standards

- (1) The rules may specify standards for a therapeutic product.
- (2) The product standards may (without limitation) relate to any of the following:

- (a) a therapeutic product itself, including anything relating to its quality, safety, or efficacy or performance;
- (b) the responsible manufacturer's quality management systems, including requirements for assessing, recording, and reporting compliance or non-compliance with product standards (known as conformity assessment procedures);
- (c) any other aspect of the product's manufacture;
- (d) the product's packaging and labelling;
- (e) the product's product or consumer information.

97 **Criteria for sponsor of approved product**

The criteria for a person to be the sponsor of an approved product are all of the following:

- (a) they are—
 - (i) an individual who is ordinarily resident in New Zealand; or
 - (ii) a body corporate that is incorporated in New Zealand; or
 - (iii) the Crown;
- (b) they do, or propose to do, 1 or more of the following activities (otherwise than on behalf of another person who meets the criteria set out in **paragraph (a)**):
 - (i) import, or arrange the importation of, the product into New Zealand;
 - (ii) manufacture the product in New Zealand, or arrange for another person to do so, for supply (whether in New Zealand or elsewhere);
- (c) if they are not the responsible manufacturer of the product, they have a contractual relationship with the responsible manufacturer that meets the criteria specified in the rules;
- (d) they consent to being a sponsor of an approved product;
- (e) they are a fit and proper person to be the sponsor of an approved product;
- (f) they are, or will be, able to comply with their obligations under **sections 116 to 118** (for example, they have sufficient knowledge, capacity, and arrangements and are readily contactable for post-market vigilance).

98 **Content of approval**

An approval must specify all of the following:

- (a) whether the product is a medicine, a medical device, or a type-4 product:

- (b) a description of the product, in accordance with any requirements specified in the regulations:
- (c) the purpose for which the product is approved:
- (d) the name and address of the sponsor:
- (e) the name of the responsible manufacturer and the address of each place at which it manufactures the product:
- (f) any conditions imposed on the approval under **section 106**:
- (g) the date on which the approval is granted:
- (h) the expiry date of the approval (if any).

99 Scope of approval

- (1) An approval of a therapeutic product approves:
 - (a) the product, as described in the approval, as at the time the approval is granted; and
 - (b) any subsequent changes to the product that are minor changes (as defined in **section 101(2)**).
- (2) The approval only approves the product for the purpose specified in the approval under **section 98(c)**.

100 Major changes results in new product

- (1) A **major change**, in relation to an approved product, means a change to the product itself or to any matter or information relating to the product that—
 - (a) may have a significant impact on the quality, safety, or efficacy or performance of the product; and
 - (b) is specified in the rules to be a major change.
- (2) If a major change occurs in relation to an approved product, the changed product is taken to be a different product (even if the change is to a matter or information relating to the product and the physical product has not itself changed).

101 Sponsor must notify Regulator of certain minor changes

- (1) The sponsor of an approved product must notify the Regulator if—
 - (a) a minor change occurs in relation to the product; and
 - (b) the change is of a kind specified in the rules to require notification under this section.
- (2) A **minor change**, in relation to an approved product, means a change to the product, or to any matter or information relating to the product, that is not a major change.
- (3) If a sponsor contravenes **subsection (1)** in circumstances that are not infringement circumstances,—
 - (a) if they do so wilfully, they commit a level A1 offence; or

- (b) if they do so recklessly, they commit a level A2 offence; or
 - (c) otherwise, they commit a level A3 offence.
- (4) A sponsor who commits an offence under **subsection (3)** is liable on conviction to the appropriate penalty set out in **section 233**.
- (5) A sponsor who contravenes **subsection (1)** in infringement circumstances commits an infringement offence and is liable to an infringement fee or a fine as set out in **section 251**.

102 Change of sponsor

- (1) An approval cannot be transferred from the sponsor to another person, except as provided for in this section.
- (2) The Regulator may, on application by the sponsor, transfer an approval to a new sponsor if the Regulator is satisfied that the proposed new sponsor meets the criteria for a sponsor in **section 97**.
- (3) If the Regulator is not so satisfied, the Regulator must refuse to accept the change in sponsor.

Duration of approval

103 Duration of approval

- (1) An approval takes effect on the date on which it is granted or on any later date specified in it.
- (2) An approval remains in force until the first of the following occurs:
- (a) if the approval specifies an expiry date, that date;
 - (b) if the regulations specify a maximum duration for the approval, the expiry of that period;
 - (c) the approval lapses under **section 104**;
 - (d) the approval is cancelled.

104 Approval lapses on death, bankruptcy, or insolvency of sponsor

An approval lapses if—

- (a) if the sponsor is an individual, the sponsor—
 - (i) dies; or
 - (ii) becomes bankrupt; or
- (b) if the sponsor is an entity, the sponsor—
 - (i) ceases to exist; or
 - (ii) becomes subject to an insolvency event (as defined in section 6(4) of the Financial Markets Conduct Act 2013).

*Conditions on approval***105 Conditions on approval**

- (1) An approval is subject to—
 - (a) any conditions specified in the rules; and
 - (b) any conditions imposed by the Regulator under **section 106**.
- (2) However, an approval is not subject to a condition specified in the rules if—
 - (a) the rules allow the condition to be disapplied by an approval; and
 - (b) the approval disapplies the condition.

106 Regulator may impose conditions

- (1) The Regulator may impose on an approval any conditions the Regulator considers appropriate—
 - (a) when the Regulator grants the approval; or
 - (b) at any time by varying the approval under **section 107**.
- (2) The Regulator may vary or remove a condition imposed under **subsection (1)** at any time by varying the approval under **section 107**.
- (3) The sponsor must comply with a condition of an approval on and from the date the condition is imposed.
- (4) An approved product does not cease to be approved because of a breach of a condition of the approval.

107 Variation of conditions of approval

- (1) The Regulator may vary an approval by imposing, varying, or removing a condition of the approval at any time by notifying the sponsor.
- (2) The Regulator may do so on application by the sponsor or on its own initiative.
- (3) The Regulator must not vary an approval under this section on its own initiative unless the Regulator has—
 - (a) given the sponsor an opportunity to comment; and
 - (b) complied with any procedural requirements specified in the regulations.
- (4) A variation takes effect on the date specified in the notice under **subsection (1)**.

*Cancellation of approval***108 Grounds to cancel approval**

There are **grounds to cancel** the approval of a product if—

- (a) the quality, safety, or efficacy or performance of the product for the purposes for which it is used is unacceptable:

- (b) the likely risks associated with the product outweigh the likely benefits of the product:
- (c) any criteria for approval referred to in **section 95(c)** are not met:
- (d) the product does not comply with—
 - (i) its approval; or
 - (ii) the specified product standards:
- (e) the sponsor does not meet any of the criteria for being the sponsor of an approved product in **section 97**:
- (f) any information in the application for the approval was misleading information:
- (g) protected active ingredient information was used when determining whether to grant the approval:
- (h) the product's sponsor has contravened a provision of this Act:
- (i) the product's responsible manufacturer has contravened a provision of this Act:
- (j) the product has—
 - (i) ceased to be a therapeutic product; or
 - (ii) become an approval-exempt product; or
 - (iii) become a prohibited product:
- (k) any grounds to cancel the approval specified in the rules exist.

109 Regulator may cancel approval if grounds exist

- (1) The Regulator may cancel an approval if satisfied that grounds to cancel the approval exist.
- (2) The Regulator must exercise the power in this section by notifying the sponsor.

110 Procedure to cancel approval

- (1) The Regulator must not cancel an approval under **section 109** unless the Regulator has—
 - (a) given the sponsor an opportunity to comment; and
 - (b) complied with any procedural requirements specified in the regulations.
- (2) This section does not apply if the product poses a significant risk of death or serious harm.

111 Regulator may cancel approval on application

The Regulator may cancel an approval on application by the sponsor by notifying the sponsor.

112 Effect of cancellation

A cancellation of an approval by the Regulator takes effect on the date on which the notice under **section 109 or 111** is given to the sponsor or on any later date specified in it.

*Therapeutic products register***113 Therapeutic products register**

- (1) The Regulator must maintain a register of therapeutic products.
- (2) The register must include details of the following:
 - (a) approved products:
 - (b) therapeutic products that the Regulator has refused to approve:
 - (c) therapeutic products for which an approval application has been made but not yet determined:
 - (d) therapeutic products the approval of which has ceased to be in force.
- (3) For each approved product, the register must include the following:
 - (a) the matters that must be specified in its approval under **section 98**:
 - (b) for a medicine, its active ingredients:
 - (c) any other information specified in the regulations.
- (4) For each product referred to in **subsection (2)(b), (c) or (d)**, the register must include the information specified in the regulations.
- (5) The register may include any other information about a product that the Regulator considers appropriate.
- (6) The Regulator must make the register publicly available.

Subpart 2—Approval-exempt products**114 Approval-exempt products**

- (1) The Regulator may, by Regulator's notice, declare a medicine, medical device, or type-4 product to be an approval-exempt product.
- (2) However, the Regulator must not do so unless satisfied that—
 - (a) making the declaration—
 - (i) is necessary or desirable in order to promote the purpose of this Act; and
 - (ii) is consistent with the principles set out in **section 4**; and
 - (b) the extent of the declaration is not broader than is reasonably necessary to address the matters that gave rise to the declaration.

115 Sponsor of approval-exempt product

- (1) In a Regulator's notice declaring a product to be an approval-exempt product, the Regulator must,—
 - (a) if the notice relates to a particular product, specify a particular identified person who is to be the sponsor of the product; or
 - (b) if the notice relates to a class of products, specify the persons who are the sponsors of those products.

Example

A notice relating to a class of products might specify that for products in that class that are manufactured in New Zealand, the responsible manufacturer is the sponsor, and for products in that class that are imported, the importer is the sponsor.

- (2) In determining who should be the sponsor of an approval-exempt product,—
 - (a) the Regulator must have regard to the desirability that the person would meet the criteria for a person to be the sponsor of an approved product in **section 97**; but
 - (b) the Regulator—
 - (i) is not bound by those criteria; and
 - (ii) is not required to individually assess potential sponsors of a class of products against those criteria.
- (3) If a class of products are declared to be approval-exempt products, the persons specified as sponsors may be described in a way that results in different batches or consignments of the product having different sponsors.

Subpart 3—Obligations of sponsors**116 Sponsor of approved product must ensure compliance with approval**

- (1) The sponsor of an approved product must—
 - (a) comply with the approval; and
 - (b) ensure that the product complies with its approval; and
 - (c) if the approval requires any other person to do, or not to do, something, ensure that the other person complies with the requirement.
- (2) If a sponsor contravenes **subsection (1)** in circumstances that are not infringement circumstances,—
 - (a) if they do so wilfully, they commit a level A1 offence; or
 - (b) if they do so recklessly, they commit a level A2 offence; or
 - (c) otherwise, they commit a level A3 offence.
- (3) A sponsor who commits an offence under **subsection (2)** is liable on conviction to the appropriate penalty set out in **section 233**.

- (4) A sponsor who contravenes **subsection (1)** in infringement circumstances commits an infringement offence and is liable to an infringement fee or a fine as set out in **section 251**.

117 Sponsor must ensure compliance with product standards

- (1) The sponsor of an approved product or an approval-exempt product must ensure that the product complies with the specified product standards.
- (2) If a sponsor contravenes **subsection (1)** in circumstances that are not infringement circumstances,—
- (a) if they do so wilfully, they commit a level A1 offence; or
 - (b) if they do so recklessly, they commit a level A2 offence; or
 - (c) otherwise, they commit a level A3 offence.
- (3) A sponsor who commits an offence under **subsection (2)** is liable on conviction to the appropriate penalty set out in **section 233**.
- (4) A sponsor who contravenes **subsection (1)** in infringement circumstances commits an infringement offence and is liable to an infringement fee or a fine as set out in **section 251**.

118 Sponsor must comply with regulations

- (1) The sponsor of an approved product or an approval-exempt product must comply with any requirements specified in the regulations in relation to any of the following:
- (a) product quality, safety, and efficacy or performance (including ongoing monitoring);
 - (b) product and consumer information for the product;
 - (c) packaging and labelling for the product;
 - (d) the release of the product for supply;
 - (e) tracing and recall of, or other market action in relation to, the product;
 - (f) record keeping, auditing, and giving information to the Regulator (including adverse information and event reporting).
- (2) Regulations specifying tracing and recall requirements may (without limitation) relate to any of the matters referred to in **section 55(4)**.
- (3) If a sponsor contravenes **subsection (1)** in circumstances that are not infringement circumstances,—
- (a) if they do so wilfully, they commit a level A1 offence; or
 - (b) if they do so recklessly, they commit a level A2 offence; or
 - (c) otherwise, they commit a level A3 offence.
- (4) A sponsor who commits an offence under **subsection (3)** is liable on conviction to the appropriate penalty set out in **section 233**.

- (5) A sponsor who contravenes **subsection (1)** in infringement circumstances commits an infringement offence and is liable to an infringement fee or a fine as set out in **section 251**.

119 Sponsor not responsible for approved products imported without consent

Sections 116 to 118 do not apply to the sponsor of an approved product in relation to a product that is imported without the sponsor's consent (whether by a person who is authorised to do so as mentioned in **section 52(1)(c)** or by a person acting unlawfully).

Subpart 4—Protection of active ingredient information about innovative medicines

120 Interpretation for this subpart

In this subpart,—

active moiety means the molecule, or part or portion of a molecule, that—

- (a) has a characteristic chemical or pharmacological property; and
- (b) is the portion of the active ingredient of a medicine that is responsible for the effect of the active ingredient

innovative medicine application means an application for approval of a medicine if—

- (a) the medicine contains an active ingredient; and
- (b) prior to the application being made, no application has been made for approval of a medicine that contains the same active moiety as that active ingredient

protected active ingredient information is information that—

- (a) is about, or relates to, the active moiety of a medicine; and
- (b) is given to the Regulator in an innovative medicine application; and
- (c) is not in the public domain when the application is made

protection period, in relation to protected active ingredient information, means a period referred to in **section 121(2) or (3)** that applies to the information.

121 Periods when protected active ingredient information may not normally be disclosed or used

- (1) During a protection period for protected active ingredient information, the Regulator must not—
- (a) disclose the information, unless permitted to do so by **section 122**; or
 - (b) use the information for the purposes of determining whether to grant any other application for approval.

- (2) The first **protection period** for protected active ingredient information starts on the date on which an application for approval of the medicine is first received, and ends on the earlier of—
 - (a) the date that is 5 years later; and
 - (b) the date on which the second protection period for the information starts.
- (3) The second **protection period** for protected active ingredient information starts on the date on which the Regulator either grants or declines the application, and ends on the date that is 5 years later.

122 Limited circumstances in which protected active ingredient information may be disclosed or used

Despite **section 121**, the Regulator may disclose or use protected active ingredient information during a protection period for the information if—

- (a) the disclosure or use is permitted by the regulations; or
- (b) the applicant (or if the application has been granted, the sponsor) agrees in writing to the disclosure or use; or
- (c) the information has entered the public domain and is therefore no longer confidential.

Part 5

Licences and permits

Subpart 1—Licences

123 What licence may authorise

- (1) A licence may be granted under **section 127** to authorise the licensee to carry on 1 or more controlled activities.
- (2) A licence may also authorise the licensee to do anything else specified in the licence that would otherwise contravene a provision of this Act.
- (3) A licence may also authorise a person other than the licensee to do anything that the licence could authorise the licensee to do.

124 Content of licence

- (1) A licence must specify all of the following:
 - (a) the licensee's name and address;
 - (b) the controlled activities that the licence authorises the licensee to carry on;
 - (c) anything else that the licence authorises the licensee to do;
 - (d) for each other person authorised by the licence,—

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- (i) their name and address (or if other persons are authorised as a class, a description of that class):
 - (ii) the controlled activities that the licence authorises them to carry on:
 - (iii) anything else that the licence authorises them to do:
 - (e) the therapeutic products covered by the licence (other than for a pharmacy licence):
 - (f) the address or a description of each relevant place:
 - (g) the names of the responsible persons for the licence:
 - (h) any conditions imposed by the Regulator under **section 139**:
 - (i) any other information specified by the regulations.
- (2) A licence may specify acts, matters, or things (including places) individually or by class.
 - (3) If, for the purposes of **section 125(1)(b)**, a licence specifies that it does not authorise the licensee's workers, the licence may authorise 1 or more of those workers under **subsection (1)(d)**.
 - (4) In this section, **relevant place** means—
 - (a) for a pharmacy licence, each place or vehicle at or from which the licence authorises 1 or more pharmacy activities to be carried on; or
 - (b) for any other licence, if the licence authorises activities to be carried on or things to be done only at certain places, each of those places.

Example

For **subsection (1)(f)**, a pharmacy licence may specify places individually or by class. It may also specify different places for different activities. So it might authorise—

- compounding, dispensing, and supplying medicines at the licensee's main shop at a specified address:
- dispensing and supplying medicines at any aged care facility in a specified district:
- supplying medicines from a pharmacy van in a specified geographical area:
- supplying from a collection depot, medicines dispensed from the licensee's main shop and sent to the collection depot for customers to pick up.

The licence may also be subject to conditions such as that medicines can only be supplied at an aged care facility for patients who are residents at the facility.

125 Effect of licence

- (1) A licence authorises—
 - (a) the licensee to carry on or do the activities or other things specified in it under **section 124(1)(b) and (c)**; and

- (b) a worker of the licensee who is acting within the scope of the worker's actual or apparent authority to do anything that the licensee is authorised by the licence to do, unless the licence specifies otherwise; and
 - (c) any other person specified in the licence to carry on or do the activities specified in it under **section 124(1)(d)(ii) or (iii)** in relation to that person.
- (2) However, any authorisation conferred by the licence—
- (a) applies only in relation to a therapeutic product covered by the licence; and
 - (b) is subject to the terms and conditions of the licence.
- (3) For a pharmacy licence, this section is subject to **section 126**.

Example

If Big Co has a licence to manufacture medicine A at its factory in Nelson, the licence only authorises Big Co to manufacture that medicine at that factory.

If Big Co manufactured medicine B, it would contravene **section 53** because that is not authorised by the licence. If Big Co manufactured medicine A at a different factory, that would also contravene **section 53** because it is not authorised by the licence.

If Big Co wants to be able to do something different from what is authorised by its licence, it would need to get its licence varied (under **section 140**) or get a new licence.

126 Effect of pharmacy licence: additional provisions

- (1) If a licence specifies under **section 124(1)(b)** that the licensee is authorised to carry on a pharmacy business,—
- (a) the licence is a pharmacy licence (*see* the definition of pharmacy licence in **section 14**); and
 - (b) the effect of **section 125(1)(a) and (b)** is that, subject to this section, the licensee and the licensee's workers may carry on that business; and
 - (c) the effect of **sections 57 to 60** is that pharmacists and pharmacy workers working in the business may carry on pharmacy activities.
- (2) However, despite the effect of **section 125(1)(a) and (b)**, a pharmacy licence—
- (a) authorises the licensee to carry on a pharmacy activity only to the extent that the pharmacy activity is carried on on behalf of the licensee by an individual who is personally authorised to carry on that pharmacy activity (whether by **sections 57 to 60** or otherwise); and
 - (b) does not authorise any other worker in the business to carry on a pharmacy activity, unless the licence specifies (under **section 124(1)(d)**) that it does.

127 Grant of licence

- (1) A person may apply to the Regulator for a licence.
- (2) If the Regulator is satisfied that the criteria for granting a licence in **section 128** are met (or will be met if the licence is granted), the Regulator may grant a licence to the person named in the application as the licensee.
- (3) If the Regulator is not satisfied that the criteria are or will be met, the Regulator must refuse to grant a licence.

128 Criteria for granting licence

- (1) The criteria for granting a licence are all of the following:
 - (a) the licensee meets the criteria for being a licensee in **section 129**;
 - (b) the number of responsible persons for the licence is not less than the number specified in the rules;
 - (c) each responsible person meets the criteria for a responsible person in **section 130**;
 - (d) the relevant resources are adequate and suitable to enable—
 - (i) all activities and other things authorised by the licence to be carried on or done in a way that will not pose an unacceptable risk of harm; and
 - (ii) all persons authorised by the licence to comply with this Act:
 - (e) the relevant persons, individually and collectively, have sufficient knowledge of the following to enable the licensee and each relevant person to comply with this Act:
 - (i) this Act and the relevant persons' obligations under it;
 - (ii) the therapeutic products covered by the licence;
 - (iii) each controlled activity or other thing authorised by the licence;
 - (f) each relevant person and any other person authorised by the licence is, or will be, able to comply with this Act;
 - (g) for a licence that authorises a person to conduct a clinical trial, that—
 - (i) an ethics approval is in force for the trial; or
 - (ii) a relevant ethics approval entity certifies that ethics approval is not required for the trial;
 - (h) any other criteria specified in the rules.
- (2) In this section,—
relevant person means any of the following:
 - (a) the licensee;
 - (b) a senior manager of the licensee;
 - (c) a responsible person

relevant resources means—

- (a) the premises, equipment, processes, and procedures used for carrying on or doing anything authorised by the licence or complying with this Act; and
- (b) the human and financial resources of the licensee and other persons authorised by the licence.

129 Criteria for licensee

The criteria for a person to be a licensee are that—

- (a) they are:
 - (i) an individual who is ordinarily resident in New Zealand; or
 - (ii) a body corporate that is incorporated in New Zealand; or
 - (iii) the Crown; and
- (b) they are a fit and proper person to be a licensee.

130 Criteria for responsible persons

The criteria for a person to be a responsible person are that—

- (a) they are an individual; and
- (b) they are ordinarily resident in New Zealand; and
- (c) they consent to being a responsible person for the licence; and
- (d) they are a fit and proper person to be a responsible person; and
- (e) they meet any qualification, training, and competency requirements specified in the rules.

Subpart 2—Permits

131 What permit may authorise

- (1) A permit may be granted under **section 134** to authorise the permit holder to do 1 or more of the following:
 - (a) import or supply a medicine, medical device, or type-4 product without it being approved or import an approved product without the sponsor's consent;
 - (b) carry on a controlled activity;
 - (c) do anything else that would otherwise contravene a provision of this Act.
- (2) A permit may also authorise a person other than the permit holder to do anything referred to in **subsection (1)**.

132 Content of permit

- (1) A permit must specify all of the following:
 - (a) the permit holder's name and address:

- (b) the controlled activities or other things that the permit authorises the permit holder to carry on or do;
 - (c) whether the permit authorises the permit holder's workers;
 - (d) for each other person authorised by the permit,—
 - (i) their name and address (or if other persons are authorised as a class, a description of that class);
 - (ii) the controlled activities or other things that the permit authorises them to carry on or do;
 - (e) the therapeutic products covered by the permit;
 - (f) if the permit authorises activities to be carried on or things to be done only at certain places, the address or a description of each of those places;
 - (g) any conditions imposed by the Regulator under **section 139**;
 - (h) any other information specified by the regulations.
- (2) A permit may specify persons, acts, matters, or things individually or by class.
- (3) If a permit does not authorise the permit holder's workers under **subsection (1)(c)**, the permit may authorise 1 or more of those workers under **subsection (1)(d)**.

133 Effect of permit

- (1) A permit authorises—
- (a) the permit holder to carry on or do the activities or other things specified in it under **section 132(1)(b)**; and
 - (b) if the permit specifies under **section 132(1)(c)** that it authorises the permit holder's workers, a worker of the permit holder who is acting within the scope of the worker's actual or apparent authority to do anything that the permit holder is authorised by the permit to do; and
 - (c) any other person specified in the permit to carry on or do the activities specified in it under **section 132(1)(d)(ii)** in relation to that person.
- (2) However, any authorisation conferred by the permit—
- (a) applies only in relation to a therapeutic product covered by the permit; and
 - (b) is subject to the terms and conditions of the permit.
- (3) A permit does not authorise a person to carry on or do any activities or other things in relation to a prohibited product unless the permit expressly states that it does.

134 Grant of permit

- (1) A person may apply to the Regulator for a permit.

- (2) If the Regulator is satisfied that the criteria for granting a permit in **section 135** are met (or will be met if the permit is granted), the Regulator may grant the permit to the person named in the application as the permit holder.
- (3) If the Regulator is not satisfied that the criteria are or will be met, the Regulator must refuse to grant the permit.

135 Criteria for granting permit

The criteria for granting a permit are all of the following:

- (a) the permit holder and any other person authorised by the permit are, or will be, able to comply with this Act:
- (b) granting the permit—
 - (i) is necessary or desirable in order to promote the purpose of this Act; and
 - (ii) is consistent with the principles set out in **section 4**:
- (c) the extent of the permit is not broader than is reasonably necessary to address the matters that gave rise to the permit:
- (d) for a permit that authorises a person to conduct a clinical trial,—
 - (i) an ethics approval is in force for the trial; or
 - (ii) a relevant ethics approval entity certifies that ethics approval is not required for the trial:
- (e) for a permit relating to a prohibited product, any criteria specified in the regulations (*see* **section 81(2)**):
- (f) any other criteria specified in the rules.

Subpart 3—Provisions applying to licences and permits

Splitting applications

136 Regulator may split application

- (1) This section applies if—
 - (a) a person applies for a licence or permit; and
 - (b) the Regulator considers that the things for which authorisation is sought would be more appropriately regulated using—
 - (i) 2 or more licences or permits; or
 - (ii) a licence and a permit; or
 - (iii) a combination of 1 or more licences and 1 or more permits.
- (2) The Regulator may treat the application as an application for the number of licences or permits or both as the Regulator considers appropriate, and grant (or refuse to grant) 1 or more licences or permits accordingly.

*Duration of licence or permit***137 Duration**

- (1) A licence—
 - (a) takes effect on the date on which it is granted or on any later date specified in it; and
 - (b) remains in force for 3 years or for any shorter period specified in it (unless it is cancelled before then).
- (2) A permit—
 - (a) takes effect on the date on which it is granted or on any later date specified in it; and
 - (b) remains in force for 2 years or for any shorter period specified in it (unless it is cancelled before then).
- (3) However, if a licensee or permit holder applies for a new licence or permit at least 20 working days before the expiry date of an existing licence or permit that the new one is intended to replace, and the application is not determined before the expiry date, the existing licence or permit continues in force until the application is determined.

*Conditions on licence or permit***138 Conditions**

- (1) A licence or permit is subject to—
 - (a) any conditions specified in the rules; and
 - (b) any conditions imposed by the Regulator under **section 139**.
- (2) However, a licence or permit is not subject to a condition specified in the rules if—
 - (a) the rules allow the condition to be disapplied by a licence or permit; and
 - (b) the licence or permit disapplies the condition.

139 Regulator may impose conditions

- (1) The Regulator may impose on a licence or permit any conditions the Regulator considers appropriate—
 - (a) when the licence or permit is granted; or
 - (b) at any time by varying the licence or permit under **section 140**.
- (2) The Regulator may vary or remove a condition imposed under **subsection (1)** at any time by varying the licence or permit under **section 140**.

*Variation of licence or permit***140 Variation**

- (1) The Regulator may vary a licence or permit at any time by notifying the licensee or permit holder.
- (2) The Regulator may do so on application by the licensee or permit holder or on its own initiative.
- (3) However, the Regulator must not do so on its own initiative unless the Regulator has given the licensee or permit holder an opportunity to comment.
- (4) A variation takes effect on the date specified in the notice under **subsection (1)**.

*Suspension and cancellation of licence or permit***141 Grounds to suspend or cancel licence**

- (1) There are **grounds to suspend or cancel** a licence if—
 - (a) any of the criteria for granting the licence in **section 128** are not met;
 - (b) the licensee has contravened a provision of this Act;
 - (c) any other person authorised by the licence has contravened a provision of this Act;
 - (d) any of the activities or other things authorised by the licence are being carried on or done in a way that poses an unacceptable risk of harm;
 - (e) any information in the application for the licence was misleading information;
 - (f) the licensee has ceased to carry on all controlled activities authorised by the licence and does not intend to resume doing so before the licence's expiry date;
 - (g) for a licence that authorises a person to conduct a clinical trial, the ethics approval for the trial, or the certificate referred to in **section 128(1)(g)(ii)**, is not complied with;
 - (h) any grounds to suspend or cancel the licence specified in the rules exist.
- (2) However, **subsection (1)(c)** does not apply if the other person's contravention does not relate to doing something that they are authorised by the licence to do.

142 Grounds to suspend or cancel permit

- (1) There are **grounds to suspend or cancel** a permit if—
 - (a) any of the criteria for granting the permit in **section 135** are not met;
 - (b) the purpose for which the permit was granted no longer exists;
 - (c) the permit holder has contravened a provision of this Act;

- (d) any other person authorised by the permit has contravened a provision of this Act:
 - (e) any of the activities or other things authorised by the permit are being carried on or done in a way that poses an unacceptable risk of harm:
 - (f) the permit holder has ceased to carry on or do the activities or other things authorised by the permit and does not intend to resume doing so before the permit's expiry date:
 - (g) any information in the application for the permit was misleading information:
 - (h) for a permit that authorises a person to conduct a clinical trial, the ethics approval for the trial, or the certificate referred to in **section 135(d)(ii)**, is not complied with:
 - (i) any grounds to suspend or cancel the permit specified in the rules exist.
- (2) However, **subsection (1)(d)** does not apply if the other person's contravention does not relate to doing something that they are authorised by the permit to do.

143 Regulator may suspend or cancel if grounds exist

- (1) The Regulator may suspend or cancel a licence or permit if satisfied that grounds to suspend or cancel exist.
- (2) A suspension may be for a specified period (not exceeding 6 months) or until a specified requirement is met.
- (3) The Regulator may suspend a licence or permit 2 or more times if grounds to suspend or cancel continue to exist.
- (4) The Regulator must exercise a power under this section by notifying the licensee or permit holder.
- (5) If the licence or permit authorises a person other than the licensee or permit holder, the Regulator must take reasonable steps to notify them of the suspension or cancellation.

144 Procedure to suspend or cancel

- (1) The Regulator must not suspend or cancel a licence or permit under **section 143** unless the Regulator has—
 - (a) given the licensee or permit holder an opportunity to comment; and
 - (b) complied with any procedural requirements specified in the regulations.
- (2) This section does not apply if the Regulator is satisfied that the suspension or cancellation is necessary because of a significant risk of death or serious harm.

145 Regulator may suspend or cancel on application

The Regulator may suspend or cancel a licence or permit on application by the licensee or permit holder by notifying the licensee or permit holder.

146 Duration of suspension

The suspension of a licence or permit by the Regulator—

- (a) takes effect on the date on which the notice under **section 143(4) or 145** is given to the licensee or permit holder or on any later date specified in it; and
- (b) remains in force until,—
 - (i) if the suspension is for a specified period, that period expires or the suspension is lifted under **section 147**; or
 - (ii) if the suspension is until a specified requirement is met, the suspension is lifted under **section 147**.

147 Lifting of suspension

- (1) If the Regulator suspends a licence or permit, the Regulator—
 - (a) may lift the suspension early if satisfied that the grounds for the suspension no longer exist; and
 - (b) if the suspension is until a specified requirement is met, must lift the suspension if satisfied that the requirement has been met.
- (2) The Regulator may exercise a power under **subsection (1)** on its own initiative or on application by the licensee or permit holder.
- (3) The Regulator must exercise a power under this section by notifying the licensee or permit holder.

148 Effect of suspension

While a licence or permit is suspended, it does not authorise any person to carry on any activity or do anything else specified in the licence or permit.

149 Effect of cancellation

A cancellation of a licence or permit by the Regulator takes effect on the date on which the notice under **section 143(4) or 145** is given to the licensee or permit holder or on any later date specified in it.

Transfer of licence or permit

150 Licence or permit not transferable

- (1) A licence or permit cannot be transferred from the licensee or permit holder to another person.
- (2) However, a licence or permit transfers automatically in the circumstances set out in **section 151**.

151 Death, bankruptcy, or insolvency of licensee or permit holder

- (1) If a licensee or permit holder dies, the licence or permit is transferred to the executor or administrator of their estate on the date and at the time of their death.
- (2) If a licensee or permit holder becomes bankrupt, the licence or permit is transferred to the Official Assignee on the date and at the time when they are adjudicated bankrupt.
- (3) If a licensee or permit holder becomes subject to an insolvency event (as defined in section 6(4) of the Financial Markets Conduct Act 2013), the licence or permit is transferred to the liquidator, administrator, receiver, statutory manager, or similar office holder on the date and at the time when the insolvency event occurred.
- (4) A person to whom a licence or permit is transferred by this section must notify the Regulator of the event that triggered the transfer within 5 working days after the event occurs.

*Register of licences and permits***152 Register of licences and permits**

- (1) The Regulator must maintain a register of licences and permits.
- (2) For each licence or permit, the register must include the following:
 - (a) the information that is required to be specified in the licence or permit under **section 124 or 132**;
 - (b) details of any suspension or cancellation of the licence or permit;
 - (c) any other information specified in the regulations.
- (3) The register may include any other information the Regulator considers appropriate.
- (4) The Regulator must make the register publicly available.

Subpart 4—Obligations of licensees and responsible persons**153 Licensee must ensure responsible person has authority and resources**

- (1) A licensee must ensure that each responsible person for the licence has sufficient authority and resources to enable the responsible person to comply with their obligations under this Act.
- (2) If a licensee contravenes **subsection (1)**—
 - (a) if they do so wilfully, they commit a level B1 offence; or
 - (b) if they do so recklessly, they commit a level B2 offence; or
 - (c) otherwise, they commit a level B3 offence.

- (3) A licensee who commits an offence under **subsection (2)** is liable on conviction to the appropriate penalty set out in **section 233**.

154 Licensee must ensure health practitioner has authority and resources

- (1) A licensee must ensure that,—
- (a) in carrying out or doing anything authorised by the licence, its health practitioner workers have sufficient authority and resources to enable them to act professionally; and
 - (b) its processes and procedures are not designed or implemented in a way that might reasonably be expected to induce a health practitioner worker to act unprofessionally.
- (2) If a licensee contravenes **subsection (1)**—
- (a) if they do so wilfully, they commit a level B1 offence; or
 - (b) if they do so recklessly, they commit a level B2 offence; or
 - (c) otherwise, they commit a level B3 offence.
- (3) A licensee who commits an offence under **subsection (2)** is liable on conviction to the appropriate penalty set out in **section 233**.

155 Licensee or manager must not induce health practitioner to act unprofessionally

- (1) A licensee, or a senior manager of a licensee, must not engage in conduct with the intention of inducing a health practitioner worker of the licensee to act unprofessionally.
- (2) A licensee or a senior manager of a licensee who contravenes **subsection (1)** commits a level B1 offence and is liable on conviction to the penalty set out in **section 233(4)**.

156 Responsible person must report non-compliance

- (1) This section applies if a responsible person for a licence becomes aware that—
- (a) a relevant person has contravened a provision of this Act, or has attempted or intends to do so; or
 - (b) any person has induced a relevant person to contravene a provision of this Act, or has attempted or intends to do so.
- (2) The responsible person must notify the licensee of the conduct referred to in **subsection (1)** as soon as practicable after becoming aware of it.
- (3) The responsible person must notify the Regulator if, after a reasonable period has elapsed since the licensee was notified,—
- (a) any contravention has not been remedied; or
 - (b) the conduct continues.

- (4) In this section, **relevant person**, in relation to a licence, means any of the following:
- (a) the licensee;
 - (b) any senior manager of the licensee;
 - (c) a person who works in the licensee's business;
 - (d) a responsible person for the licence;
 - (e) any other person authorised by the licence.

157 Protection of responsible person from retaliation

- (1) A licensee, or a senior manager of a licensee, must not engage in adverse conduct in relation to a responsible person for a retaliatory reason.
- (2) A person (**person A**) engages in **adverse conduct** in relation to a responsible person if person A—
- (a) does any of the following:
 - (i) terminates the arrangement under which the responsible person works for the licensee;
 - (ii) terminates the responsible person's nomination as a responsible person;
 - (iii) alters the responsible person's position as a worker to their detriment;
 - (iv) treats the responsible person less favourably in relation to their work than other comparable workers;
 - (v) subjects the responsible person to any other detriment in relation to their work to which other comparable workers are not subjected; or
 - (b) induces another person to do anything referred to in **paragraph (a)**; or
 - (c) threatens to do anything referred to in **paragraph (a) or (b)**.
- (3) A person engages in adverse conduct for a **retaliatory reason** if they engage in the adverse conduct—
- (a) because the responsible person complies with their obligations, or complies with them in a particular way; or
 - (b) to prevent the responsible person from complying with their obligations, or from complying with them in a particular way; or
 - (c) to induce the responsible person to comply with their obligations in a particular way, or to not comply with them.
- (4) A licensee, or a senior manager of a licensee, who contravenes **subsection (1)** commits a level B1 offence and is liable on conviction to the penalty set out in **section 233(4)**.
- (5) In this section,—

comply includes has complied, is complying, or proposes to comply

obligation means an obligation under this Act.

158 Responsible person must comply with regulations

- (1) A responsible person for a licence must comply with any requirements set out in the regulations in relation to any of the following:
 - (a) quality control and assurance in relation to the carrying on of activities authorised by the licence:
 - (b) record keeping, auditing, and giving information to the Regulator:
 - (c) tracing and recall of therapeutic products:
 - (d) qualifications, training, and competency of—
 - (i) responsible persons:
 - (ii) workers in the licensee’s business:
 - (e) oversight of the day-to-day operation of the activities of the licensee.
- (2) Regulations specifying tracing and recall requirements may (without limitation) relate to any of the matters referred to in **section 55(4)**.
- (3) If a responsible person contravenes **subsection (1)** in circumstances that are not infringement circumstances,—
 - (a) if they do so wilfully, they commit a level B1 offence; or
 - (b) if they do so recklessly, they commit a level B2 offence; or
 - (c) otherwise, they commit a level B3 offence.
- (4) A responsible person who commits an offence under **subsection (3)** is liable on conviction to the appropriate penalty set out in **section 233**.
- (5) A responsible person who contravenes **subsection (1)** in infringement circumstances commits an infringement offence and is liable to an infringement fee or a fine as set out in **section 251**.

159 Licensee must ensure only authorised persons carry on pharmacy activities

- (1) The licensee of a pharmacy licence must ensure that no unauthorised pharmacy activity is carried on at or from a place or vehicle specified in the licence under **section 124(1)(f)**.
- (2) A pharmacy activity is **unauthorised** if it is carried on—
 - (a) by a person who is not authorised to do so; or
 - (b) when a pharmacist is not present at the place or vehicle.
- (3) If a licensee contravenes **subsection (1)**—
 - (a) if they do so wilfully, they commit a level B1 offence; or
 - (b) if they do so recklessly, they commit a level B2 offence; or

- (c) otherwise, they commit a level B3 offence.
- (4) A licensee who commits an offence under **subsection (3)** is liable on conviction to the appropriate penalty set out in **section 233**.

Part 6

Regulator

Subpart 1—Regulatory powers and functions

Safety monitoring

160 Regulator to monitor safety

- (1) The Regulator must ensure it has in place a system to continuously monitor the safety of the following products in accordance with any requirements specified in the regulations—
 - (a) approved products; and
 - (b) approval-exempt products; and
 - (c) unapproved products that are lawfully imported or supplied without being approved.
- (2) The regulations may (without limitation) specify:
 - (a) the nature and scope of monitoring to be undertaken;
 - (b) how and when monitoring is to be undertaken;
 - (c) circumstances in which monitoring is not required;
 - (d) information that the Regulator must give to persons or make publicly available about monitoring.

Public safety announcements

161 Public safety announcements

- (1) For the purpose of protecting personal and community health, the Regulator may make a statement relating to 1 or more of the following:
 - (a) a therapeutic product;
 - (b) an advertisement or other information about a therapeutic product;
 - (c) a sponsor or person in the supply chain.
- (2) A statement may specify persons, acts, matters, or things individually or by class.
- (3) The Regulator may—
 - (a) include in the statement any information the Regulator consider appropriate; and
 - (b) publish the statement in any way the Regulator consider appropriate.

- (4) However, to the extent that a statement relates to a sponsor or person in the supply chain, the Regulator must not make the statement unless satisfied that the scope of the statement is not broader than is reasonably necessary for the purpose for which it is made.
- (5) No proceedings (whether civil or criminal), other than proceedings for judicial review, may be brought against the Regulator or the Crown or any other person in respect of a statement made under this section in good faith.

Regulatory orders

162 Recall order

- (1) The Regulator may make a recall order for a therapeutic product if satisfied that the continued availability of the product poses an unacceptable risk of harm.
- (2) A **recall order** for a therapeutic product is an order directing the product's sponsor or a person in the supply chain to do 1 or more of the following:
 - (a) recall the product from all or part of the supply chain;
 - (b) dispose of or destroy the product;
 - (c) return or deliver the product to a specified person;
 - (d) not to use the product until it has been inspected, tested, repaired, modified, or otherwise dealt with;
 - (e) take any other steps specified in the order relating to—
 - (i) the removal of the product from the supply chain; or
 - (ii) reducing the risk posed by the product.
- (3) A recall order may also prohibit a person in the supply chain from carrying on 1 or more supply chain activities with the product.

163 Compliance with recall order

- (1) A person who has been given a recall order by the Regulator must comply with it.
- (2) If a recall order includes a prohibition under **section 162(3)**, a person in the supply chain who has been given a copy of the order by the product's sponsor must also comply with the order.
- (3) If a person contravenes **subsection (1) or (2)**,—
 - (a) if they do so wilfully, they commit a level A1 offence; or
 - (b) if they do so recklessly, they commit a level A2 offence; or
 - (c) otherwise, they commit a level A3 offence.
- (4) A person who commits an offence under **subsection (3)** is liable on conviction to the appropriate penalty set out in **section 233**.

164 Premises restriction order

- (1) The Regulator may make a premises restriction order for a place or vehicle for a supply chain activity if satisfied that the use of the place or vehicle for the activity poses an unacceptable risk of harm.
- (2) A **premises restriction order** is an order prohibiting the use, in the course of a business, of a specified place or vehicle for, or in relation to, the carrying on of a specified supply chain activity.

165 Compliance with premises restriction order

- (1) A person who has been given a premises restriction order by the Regulator—
 - (a) must not use the place or vehicle in contravention of the order; and
 - (b) if they are an owner or occupier of the place or vehicle, must not permit the place or vehicle to be used in contravention of the order.
- (2) If a person contravenes **subsection (1)**,—
 - (a) if they do so wilfully, they commit a level A1 offence; or
 - (b) if they do so recklessly, they commit a level A2 offence; or
 - (c) otherwise, they commit a level A3 offence.
- (3) A person who commits an offence under **subsection (2)** is liable on conviction to the appropriate penalty set out in **section 233**.

166 Advertising remediation order

- (1) The Regulator may make an advertising remediation order if satisfied that a person (the **advertiser**) has distributed, or caused the distribution of, an advertisement for a therapeutic product in contravention of **section 83**.
- (2) An **advertising remediation order** is an order directing the advertiser, or a person involved in the distribution of the advertisement, to do 1 or more of the following:
 - (a) retrieve the advertisement from distribution:
 - (b) dispose of or destroy the advertisement:
 - (c) remove the advertisement from any Internet site under the person's control:
 - (d) distribute a retraction or correction:
 - (e) take any other steps specified in the order relating to—
 - (i) preventing the continued or further distribution of the advertisement; or
 - (ii) reducing the risk of harm posed by the advertisement.

167 Compliance with advertising remediation order

- (1) A person who has been given an advertising remediation order by the Regulator must comply with it.

- (2) If a person contravenes **subsection (1)**,—
- (a) if they do so wilfully, they commit a level B1 offence; or
 - (b) if they do so recklessly, they commit a level B2 offence; or
 - (c) otherwise, they commit a level B3 offence.
- (3) A person who commits an offence under **subsection (2)** is liable on conviction to the appropriate penalty set out in **section 233**.

168 Directions order

- (1) The Regulator may make a directions order in relation to a therapeutic product if satisfied that—
- (a) there is a significant risk of death or serious harm in relation to the product; and
 - (b) making the directions order—
 - (i) is necessary or desirable in order to promote the purpose of this Act; and
 - (ii) is consistent with the principles set out in **section 4**; and
 - (c) the extent of the order is not broader than is reasonably necessary to address the risk that gave rise to the order.
- (2) A **directions order** is an order that directs a person to do, or not to do, something specified in the order in relation to a therapeutic product.

169 Compliance with directions order

- (1) A person who has been given a directions order by the Regulator must comply with it.
- (2) If a person contravenes **subsection (1)**,—
- (a) if they do so wilfully, they commit a level B1 offence; or
 - (b) if they do so recklessly, they commit a level B2 offence; or
 - (c) otherwise, they commit a level B3 offence.
- (3) A person who commits an offence under **subsection (2)** is liable on conviction to the appropriate penalty set out in **section 233**.

170 Product prohibition order

- (1) The Regulator may make a product prohibition order for a therapeutic product if satisfied that—
- (a) the product poses a significant risk of death or serious harm; and
 - (b) that risk cannot be adequately managed by the exercise of the Regulator's other powers under this Act.

-
- (2) A **product prohibition order** is an order that prohibits any person from doing any of the following (**prohibited activities**) in relation to a specified therapeutic product:
- (a) importing the product:
 - (b) manufacturing the product:
 - (c) supplying the product:
 - (d) for a medicine:
 - (i) prescribing the medicine:
 - (ii) administering the medicine:
 - (e) for a medical device or type-4 product, using the product on a patient:
 - (f) taking the product overseas:
 - (g) possessing the product.
- (3) However, the order may allow a person to carry on 1 or more of the prohibited activities in specified circumstances.

171 Compliance with product prohibition order

- (1) A person must comply with a product prohibition order if—
- (a) the person has been given the order by the Regulator; or
 - (b) for a person in the supply chain, the person—
 - (i) knows that the order is in force; or
 - (ii) is reckless as to whether the order is in force; or
 - (c) for a person not in the supply chain, the person knows that the order is in force.
- (2) If a person contravenes **subsection (1)**,—
- (a) if they do so wilfully, they commit a level A1 offence; or
 - (b) if they do so recklessly, they commit a level A2 offence; or
 - (c) otherwise, they commit a level A3 offence.
- (3) A person who commits an offence under **subsection (2)** is liable on conviction to the appropriate penalty set out in **section 233**.

172 Regulator's powers in relation to oversupplied persons

- (1) If the Regulator believes that an individual is an oversupplied person, the Regulator may do either or both of the following:
- (a) make a medicine access limitation order in relation to the person under **section 173**:
 - (b) make a statement about the person under **section 175**.
- (2) An individual is an **oversupplied person** if—

- (a) the individual—
 - (i) is addicted or habituated to a category 1 or 2 medicine; or
 - (ii) has, over a period of time, obtained, or obtained prescriptions for, a quantity of category 1 or 2 medicine that is greater than is reasonably necessary for their own therapeutic use; and
 - (b) the individual might reasonably be expected to continue to seek to obtain more of the medicine (other than as is reasonably necessary for their own therapeutic use).
- (3) The Regulator’s powers under this section and **sections 173 and 175** may be exercised only—
- (a) by the Regulator in person and after having regard to the advice of a medical practitioner; or
 - (b) by a medical practitioner to whom that power has been delegated by the Regulator.

173 Medicine access limitation order

- (1) The Regulator may make a medicine access limitation order in relation to an individual if the Regulator believes that the individual is an oversupplied person.
- (2) A **medicine access limitation order** is an order relating to a particular identified individual (the **limited-access patient**) that—
- (a) prohibits any person doing either of the following:
 - (i) supplying 1 or more specified category 1 or 2 medicines (**limited-access medicines**) to the limited-access patient;
 - (ii) prescribing a limited-access medicine for the limited-access patient; and
 - (b) prohibits the limited-access patient from obtaining, or attempting to obtain, a limited-access medicine or a prescription for a limited-access medicine.
- (3) However, a medicine access limitation order may permit the supply or prescribing of a limited-access medicine to or for the limited-access patient by a specified person in specified circumstances.

174 Compliance with medicine access limitation order

- (1) A person must not supply or prescribe a medicine in contravention of a medicine access limitation order if—
- (a) the person has been given the order by the Regulator; or
 - (b) the person knows that, or is reckless as to whether, the order is in force.
- (2) A limited-access patient who has been given the order by the Regulator must comply with it.

- (3) If a person contravenes **subsection (1)**,—
 - (a) if they do so wilfully, they commit a level B1 offence; or
 - (b) if they do so recklessly, they commit a level B2 offence; or
 - (c) otherwise, they commit a level B3 offence.
- (4) A person who commits an offence under **subsection (3)** is liable on conviction to the appropriate penalty set out in **section 233**.
- (5) A limited-access patient who contravenes **subsection (2)** commits a level B3 offence and is liable on conviction to the penalty set out in **section 233(6)**.

175 Statement about oversupplied person

- (1) If the Regulator believes that an individual is an oversupplied person, the Regulator may make a statement about the individual for the purpose of doing either or both of the following:
 - (a) limiting the supply of category 1 or 2 medicines to the individual:
 - (b) assisting in the treatment of the individual's addiction or habit.
- (2) The Regulator may include in the statement any information the Regulator consider necessary for those purposes.
- (3) The Regulator may disclose the statement only to 1 or more of the notifiable persons, but may do so in any way the Regulator consider appropriate.
- (4) No proceedings (whether civil or criminal), other than proceedings for judicial review, may be brought against the Regulator or the Crown or any other person in respect of a statement made under this section in good faith.
- (5) In this section, **notifiable person** means any of the following:
 - (a) a health practitioner who is a prescriber for 1 or more medicines:
 - (b) a pharmacist:
 - (c) a person who is authorised under this Act to supply by non-wholesale supply, prescribe, or administer, in the course of business, a medicine to which the statement relates:
 - (d) a person working in the Ministry:
 - (e) a DHB (as defined in section 6(1) of the New Zealand Public Health and Disability Act 2000) or a person working for a DHB:
 - (f) a person who provides hospital care (as defined in section 4(1) of the Health and Disability Services (Safety) Act 2001) or a person who works for such a provider:
 - (g) a manager of a treatment centre (as defined in section 4 of the Substance Addiction (Compulsory Assessment and Treatment) Act 2017):
 - (h) a prison manager (as defined in section 3(1) of the Corrections Act 2004):

- (i) the Commissioner of Police under the Policing Act 2008 or a Police employee (as defined in section 4 of that Act);
- (j) a responsible authority under the Health Practitioners Competence Assurance Act 2003;
- (k) the Health and Disability Commissioner under the Health and Disability Commissioner Act 1994 or a person who works for the Commissioner.

176 Information in statement to be kept confidential

*Information in a statement about the person under **section 175** is personal information (as defined in the Privacy Act 1993). To ensure that the information is not disclosed inappropriately, it is intended to provide a person about whom such a statement is made with the ability to complain to the Privacy Commissioner if they believe their privacy has been breached (which would in turn open up a route to complain to the Human Rights Tribunal).*

If the Privacy Bill, which is currently before Parliament, is passed, it will replace the Privacy Act 1993. The new Privacy Bill will contain a similar mechanism although the precise details may not be exactly the same as the Privacy Act 1993. Drafting of this section has therefore been deferred until the Privacy Bill is passed (or it is decided that this Bill should proceed on the basis of the Privacy Act 1993).

Provisions applying to all regulatory orders

177 Content of regulatory orders

- (1) A regulatory order may specify how, and by when, anything required by the order must be done.
- (2) A regulatory order may (subject to the provision under which it is made)—
 - (a) specify persons, acts, matters, or things individually or by class;
 - (b) make different provision for different cases on any differential basis;
 - (c) make provision for things either unconditionally or subject to conditions;
 - (d) be made on any terms the Regulator considers appropriate.
- (3) A regulatory order may also request persons who are not required to comply with the order to do anything that could be required by the order.

Example

A recall order that requires the product sponsor to recall the product might also request members of the public to return the product to the shop where they bought it even though members of the public are not required to comply with the order.

- (4) A directions order or product prohibition order must specify in it the date on which it expires, which must not be more than 12 months after it is made.

178 Making regulatory order

- (1) The Regulator must not make a regulatory order (other than a medicine access limitation order) unless the Regulator has given all affected persons an opportunity to comment.
- (2) The **affected persons** are,—
 - (a) for a recall order, directions order, or product prohibition order for an approved product or approval-exempt product, the product's sponsor;
 - (b) for a premises restriction order, a person who—
 - (i) is an owner or occupier of the place or vehicle; or
 - (ii) uses the place or vehicle for a supply chain activity specified in the order;
 - (c) for an advertising remediation order,—
 - (i) the person who distributed the advertisement; and
 - (ii) if another person caused the distribution of the advertisement, that person.
- (3) If the Regulator makes a product prohibition order,—
 - (a) the Regulator must make it publicly available; and
 - (b) the order takes effect on the day after the date on which it is published on the Regulator's Internet site or on any later date specified in it.

179 Regulatory orders in relation to something misrepresented to be therapeutic product

- (1) The Regulator may make any of the following regulatory orders in relation to something that has been represented as being a therapeutic product in breach of **section 88(1)(a)** (even though it is not a therapeutic product):
 - (a) a recall order;
 - (b) an advertising remediation order;
 - (c) a directions order;
 - (d) a product prohibition order.
- (2) For that purpose, the provisions of this Act relating to an order of that sort apply as if the misrepresented thing were an unapproved therapeutic product.

180 Regulatory order overrides other provisions of Act

A regulatory order has effect,—

- (a) if the order prohibits a person from doing something, even if the person is authorised by a licence, permit, or provision of **subpart 3 of Part 3** to do the thing; and
- (b) if the order requires a person to do something, even if the person would otherwise be prohibited under this Act from doing the thing.

181 Variation of regulatory orders

- (1) The Regulator may vary a regulatory order—
 - (a) on application by—
 - (i) a person who is required to comply with the order; or
 - (ii) if the order (other than a medicine access limitation order) relates to an approved product or approval-exempt product, the product's sponsor; or
 - (b) on its own initiative.
- (2) However, the Regulator must not vary an order so as to make it more onerous unless the Regulator has given all affected persons (as defined in **section 178**) an opportunity to comment.
- (3) A person who was given the original order is only required to comply with the order as varied after being given notice of the variation.
- (4) **Section 178(3)** applies to a variation of a product prohibition order.

182 Revocation of regulatory order

- (1) The Regulator may revoke a regulatory order—
 - (a) on application by—
 - (i) a person who is required to comply with the order; or
 - (ii) if the order (other than a medicine access limitation order) relates to an approved product or approval-exempt product, the product's sponsor; or
 - (b) on its own initiative.
- (2) The Regulator must—
 - (a) give notice of the revocation to all persons who were given the order; and
 - (b) take reasonable steps to ensure that other persons who were required to comply with the order are notified of its revocation.

Subpart 2—Investigative powers*Preliminary provisions***183 Interpretation for investigative powers**

In this subpart,—

evidential material has the same meaning as in section 3(1) of the Search and Surveillance Act 2012

investigative purposes means any of the following:

- (a) investigating compliance with this Act, including ascertaining—

- (i) whether this Act applies in relation to a person, an activity, or a thing, or in a particular circumstance:
 - (ii) whether an approved product complies with its approval or whether an approval-exempt product is covered by its declaration of approval-exemption:
 - (iii) whether a person is complying with an approval, a licence, or a permit:
- (b) obtaining evidential material in relation to an offence or a suspected offence against this Act:
 - (c) obtaining information to enable the Regulator to perform its functions and exercise its powers under **subpart 1 of Part 6** (regulatory powers and functions)

issuing officer has the same meaning as in section 3(1) of the Search and Surveillance Act 2012

place includes a vehicle

relevant thing, in relation to the exercise of powers under this subpart, means any thing found or obtained under this subpart that is relevant for investigative purposes

seized thing means a thing that is seized—

- (a) by the Regulator under this Act; or
- (b) by a Customs officer under section 242(1)(b)(v) of the Customs and Excise Act 2018.

184 How powers are exercised

- (1) The powers in this subpart may be exercised—
 - (a) by the Regulator in person; or
 - (b) by a person who the Regulator believes is suitably qualified or trained to exercise the power and to whom the Regulator has delegated the power; or
 - (c) by a person who is a member of a class of persons who the Regulator believes are suitably qualified or trained to exercise the power and to whom the Regulator has delegated the power.
- (2) The Regulator may exercise a power under this subpart—
 - (a) at any place that the Regulator has entered using a power of entry; or
 - (b) at any other place where the Regulator may lawfully be.
- (3) The Regulator may exercise a power in this subpart (for example, to ask someone to do something) by any means of communications that is reasonable in the circumstances, unless this Act requires otherwise.

*Information gathering***185 Regulator may require information**

- (1) For investigative purposes, the Regulator may require a person (**person A**) to—
 - (a) give to the Regulator any specified relevant information (including personal information) that is within person A's possession or control (including to answer questions):
 - (b) in relation to a specified relevant document that is within person A's possession or control,—
 - (i) produce the document and allow the Regulator to copy it:
 - (ii) give a copy of the document to the Regulator:
 - (c) if person A is the sponsor of a product, obtain any specified relevant information about the product and give it to the Regulator.
- (2) The Regulator may do so only—
 - (a) if person A is, or was at a relevant time,—
 - (i) an approval holder, sponsor, or person in the supply chain; or
 - (ii) a worker of a person referred to in **subparagraph (i)**; or
 - (b) if the Regulator believes that—
 - (i) an offence against this Act has been, is being, or is likely to be committed; and
 - (ii) the information or document is evidential material in relation to the offence; or
 - (c) if the Regulator believes that obtaining the information or document is necessary—
 - (i) because of a significant risk of death or serious harm; or
 - (ii) to enable the Regulator to perform its functions and exercise its powers under **subpart 1 of Part 6** (regulatory powers and functions).
- (3) The Regulator may specify how, and by when, anything required under **subsection (1)** must be done.
- (4) Subpart 5 of Part 4 of the Search and Surveillance Act 2012 (privilege and confidentiality) applies to a requirement made, and to information obtained, under this section.

*Testing of samples***186 Testing of samples for investigative purposes**

The Regulator may, for investigative purposes,—

- (a) require the sponsor of a product to arrange for an analyst to test a sample of any relevant thing and provide the results to the Regulator:
- (b) test a sample, or arrange for testing by an analyst of a sample, of any relevant thing.

187 Laboratories and analysts

- (1) The Regulator may, by Regulator's notice, do either or both of the following:
 - (a) designate a laboratory as a recognised laboratory:
 - (b) designate a person who works at a recognised laboratory as the analyst in charge of the laboratory.
- (2) The analyst in charge of a recognised laboratory may, in writing, nominate a person who works at the laboratory as an analyst for the purposes of this Act.

188 Imported consignments may be detained pending testing

- (1) If the Regulator exercises a power under **section 186** in relation to a thing that is subject to the control of Customs, the Regulator may direct Customs to detain the thing while the testing is carried out.
- (2) If the Regulator gives a direction under **subsection (1)**, Customs must detain the thing and keep it subject to the control of Customs until the first of the following occurs:
 - (a) the Regulator directs Customs to release the thing:
 - (b) the thing becomes a seized thing:
 - (c) 20 working days expires after the day on which the direction was given.
- (3) If a thing is detained under this section, section 159 of the Search and Surveillance Act 2012 applies as if the thing had been seized by the Regulator.
- (4) In this section, **subject to the control of Customs** has the same meaning as in section 6 of the Customs and Excise Act 2018.

Powers of entry and inspection

189 Entry and inspection without warrant

- (1) For investigative purposes, the Regulator may enter and inspect a place described in **subsection (2)** without a search warrant.
- (2) The places are—
 - (a) any place at which a licence or permit authorises anything to be done:
 - (b) any place at which the Regulator reasonably believes—
 - (i) a supply chain activity is being carried on; or
 - (ii) there is information, documents, or equipment relating to the carrying on of a supply chain activity; or

- (iii) there are therapeutic products, or ingredients or components for therapeutic products, that are intended for use in a supply chain activity.
- (3) However, *see* **section 190** (homes and other special places).
- (4) The provisions of Part 4 of the Search and Surveillance Act 2012 (except subpart 3, sections 118 and 119, and subpart 8) apply in relation to the exercise of a power under this section.

190 Homes and other special places

- (1) The Regulator may not enter any land or building that is a home, a marae, or a building associated with a marae except with the consent of an occupier or under a search warrant.
- (2) Any exercise of a power of entry at a marae or a building associated with a marae must take account of the kawa of the marae so far as practicable in the circumstances.
- (3) The Regulator may not enter a treatment room while a patient is being treated in the room except with the consent of the patient or under a search warrant.
- (4) Any exercise of a power of entry at a treatment room while a patient is being treated in the room must take account of patient privacy and well-being so far as practicable in the circumstances.
- (5) This section applies despite any other provision of this subpart or the Search and Surveillance Act 2012.
- (6) In this section, **treatment room** means a part of a hospital, health care facility, or other place at which a health practitioner or other person carries on business that is used for the treatment of patients.

191 Entry and inspection with warrant

- (1) The Regulator may enter and inspect any place if authorised to do so by a search warrant.
- (2) The Regulator may apply to an issuing officer for a warrant.
- (3) An issuing officer may issue a warrant if the officer believes that—
 - (a) an offence against this Act has been, is being, or is intended to be committed; and
 - (b) there is evidential material in relation to the offence at the place.
- (4) The provisions of Part 4 of the Search and Surveillance Act 2012 (except sections 118 and 119 and subpart 8) apply in relation to the exercise of a power under this section.

192 Power to require things to be held unaltered

- (1) The Regulator may, whenever lawfully in a place, require the occupier to hold any relevant thing at the place in an unaltered state for a reasonable period.

- (2) This section does not limit Part 4 of the Search and Surveillance Act 2012.

Other matters

193 Destruction of seized things

- (1) **Subsection (2)** applies in relation to a seized thing if,—
- (a) if it is a therapeutic product, the Regulator believes that there is a risk that its safety, quality, or efficacy or performance may be unacceptable; or
 - (b) the Regulator believes that—
 - (i) it has been used for an activity that is unlawful under this Act; or
 - (ii) if it is released to the person from whom it was seized or to another person entitled to it, it is likely to be used for an activity that is unlawful under this Act; or
 - (c) all of the following apply:
 - (i) the thing was imported;
 - (ii) the importer has been given a requirement under **section 194** in relation to the thing;
 - (iii) the importer has not complied with that requirement.
- (2) Section 160 of the Search and Surveillance Act 2012 (which applies to the disposal of unlawful items) applies to the thing as if it were an item the possession of which by the person from whom it was seized or who was required to produce it is unlawful under New Zealand law.

194 Removal from New Zealand of seized things that were imported

- (1) This section applies to a seized thing if it was imported into New Zealand.
- (2) The Regulator may require the person who imported the thing to return it to its place of origin or otherwise remove it from New Zealand.
- (3) If the person does not comply with the requirement within the time specified in it, the Regulator may return the thing to its place of origin or otherwise remove it from New Zealand.

195 Cost recovery

- (1) If the Regulator or Customs incurs seizure-related costs in relation to a seized thing, the Regulator may recover those costs from 1 or more of the following:
- (a) any person convicted of an offence in relation to the seized thing;
 - (b) the owner of the thing;
 - (c) the person from whom the thing was seized;
 - (d) for costs incurred by the Regulator in returning or removing the thing from New Zealand under **section 194**, the importer.

- (2) In this section, **seizure-related costs**, in relation to a seized thing, means any costs reasonably incurred in relation to seizing the thing or dealing with it after it was seized (including transporting or storing it, returning it or removing it from New Zealand, or destroying it).

196 Customs information

The chief executive of Customs must give to the Regulator any information that the Regulator requests for investigative purposes and that is in a category referred to in section 316(2)(a) or (b)(i) or (vii) of the Customs and Excise Act 2018.

Subpart 3—Offences relating to Regulator

197 Misleading information to Regulator

- (1) A person must not give misleading information to the Regulator for the purposes of this Act.
- (2) If a person contravenes **subsection (1)** in circumstances that are not infringement circumstances,—
- (a) if they know that the information is misleading information, they commit a level B1 offence; or
 - (b) if they are reckless as to whether the information is misleading information, they commit a level B2 offence; or
 - (c) otherwise, they commit a level B3 offence.
- (3) A person who commits an offence under **subsection (2)** is liable on conviction to the appropriate penalty set out in **section 233**.
- (4) A person who contravenes **subsection (1)** in infringement circumstances commits an infringement offence and is liable to an infringement fee or a fine as set out in **section 251**.

198 Compliance with investigative requirements

- (1) A person who has been given a requirement under **section 185(1), 186(a), 192, or 194** must comply with it.
- (2) If a person contravenes **subsection (1)**,—
- (a) if they do so wilfully, they commit a level B1 offence; or
 - (b) if they do so recklessly, they commit a level B2 offence; or
 - (c) otherwise, they commit a level B3 offence.
- (3) A person who commits an offence under **subsection (2)** is liable on conviction to the appropriate penalty set out in **section 233**.

199 Obstructing Regulator

- (1) A person must not obstruct, hinder, or resist the Regulator in the exercise of a power under this Act.
- (2) If a person contravenes **subsection (1)**,—
 - (a) if they do so wilfully, they commit a level B1 offence; or
 - (b) if they do so recklessly, they commit a level B2 offence.
- (3) A person who commits an offence under **subsection (2)** is liable on conviction to the appropriate penalty set out in **section 233**.

Subpart 4—Review of Regulator’s decisions**200 Application for review of Regulator’s decision**

- (1) A person may apply to have a decision of the Regulator reviewed if—
 - (a) the decision is listed in **Schedule 2** as a reviewable decision; and
 - (b) the person is listed in **Schedule 2** as a person who may apply for a review of that decision.
- (2) To apply, the applicant must—
 - (a) make an application to the Regulator—
 - (i) within 30 working days after notice of the decision is given to the applicant under **section 208**; and
 - (ii) in the way specified in the regulations; and
 - (b) comply with any procedural requirements specified in the regulations; and
 - (c) pay the specified fee.

201 Regulator to convene review panel

- (1) On receiving an application to have a decision reviewed (the **original decision**), the Regulator must convene a review panel in accordance with any requirements specified in the regulations.
- (2) The review panel must consist of at least 3 persons—
 - (a) who the Regulator considers have appropriate knowledge, skills, and experience to enable the panel to perform its functions; and
 - (b) who were not involved in making the original decision; and
 - (c) who do not have any conflict of interest in relation to the original decision; and
 - (d) at least 1 of whom is a lawyer (as defined in section 6 of the Lawyers and Conveyancers Act 2006) with at least 7 years’ legal experience.

202 Procedure on review

- (1) A review panel must review the merits of the original decision on the basis of information that was available to the Regulator when the original decision was made.
- (2) The review panel must act—
 - (a) independently; and
 - (b) in accordance with the principles of natural justice; and
 - (c) in accordance with any procedure specified in the regulations.
- (3) The review panel may otherwise determine its own procedure.

203 Decision on review

- (1) After reviewing the original decision, the review panel must—
 - (a) confirm the original decision; or
 - (b) set aside the original decision and refer the matter back to the Regulator for the Regulator to make a new decision.
- (2) The review panel must notify the applicant and Regulator of its decision.
- (3) If the matter is referred back to the Regulator, the Regulator must—
 - (a) reconsider the matter in accordance with any recommendations made by the review panel; and
 - (b) make a new decision.

204 Appeal to District Court

- (1) If the review panel confirms the original decision under **section 203(1)(a)**, the applicant for review may appeal to the District Court against the Regulator's original decision.
- (2) If—
 - (a) the review panel sets aside the original decision and refers the matter back to the Regulator under **section 203(1)(b)**; and
 - (b) the Regulator has made a new decision on the matter—the applicant for review of the original decision may appeal to the District Court against the Regulator's new decision.
- (3) An appeal is to be made and dealt with in accordance with the District Court Rules 2014.

Subpart 5—Administrative matters relating to Regulator**205 Functions and powers generally**

- (1) The Regulator, as the chief executive of the Ministry, has all of the functions, responsibilities, duties, and powers of a chief executive under the State Sector Act 1988.

- (2) Subject to **sections 172(3) and 184**, the Regulator may delegate any of the Regulator's functions or powers under this Act in accordance with section 41 of the State Sector Act 1988.

Decision making and exercise of powers

206 Meaning of opportunity to comment

- (1) If the Regulator is required under this Act to give a person an **opportunity to comment** before a power is exercised, before exercising the power the Regulator must—
- (a) notify the person of the Regulator's intention to exercise the power and the reasons for doing so; and
 - (b) allow the person a reasonable time (specified in the notice) to make submissions on the matter to the Regulator; and
 - (c) take any submissions made in that time into account.
- (2) However, the Regulator need not comply with **subsection (1)** if—
- (a) all of the persons who the Regulator would otherwise need to notify—
 - (i) requested the Regulator to exercise the power; or
 - (ii) agree to it being exercised without **subsection (1)** being complied with; or
 - (b) the Regulator is satisfied that exercising the power without compliance with **subsection (1)** is necessary because of a significant risk of death or serious harm.

207 Regulator may rely on recognised authorities

- (1) For the purpose of making a decision under this Act, the Regulator may rely on reports, assessments, or decisions made by, or information received from, a recognised authority.
- (2) The Regulator may, by Regulator's notice, designate a person or body as a recognised authority.
- (3) In deciding whether to designate a recognised authority, the Regulator must have regard to any recognition criteria specified in the regulations.

208 Notice and reasons for decision by Regulator

- (1) This section applies if a provision of this Act—
- (a) provides for the Regulator to exercise a power or perform a function by notifying a person (for example, **section 140** allows the Regulator to vary a licence by notifying the licensee); or
 - (b) requires the Regulator to notify a person of a decision made by the Regulator.
- (2) The notice must set out—

- (a) the Regulator's decision; and
 - (b) either—
 - (i) the reasons for the decision; or
 - (ii) that the person is entitled to ask for a statement of reasons; and
 - (c) the person's right to apply for a review of the decision under **section 200** (if applicable).
- (3) If **subsection (1)(b)** applies, the Regulator must give the notice as soon as practicable after making the decision.
- (4) A person in relation to whom the Regulator has made a decision under this Act may ask the Regulator for a statement of its reasons for the decision (whether or not the person has been given a notice under **subsection (2)**).
- (5) If asked, the Regulator must notify the person of the reasons for the decision—
- (a) within the time specified in the regulations; or
 - (b) if no time is specified, within a reasonable time of being asked.

Information sharing

209 Sharing of information with regulatory agencies, etc

- (1) The Regulator may give to a regulatory entity, an overseas regulator, or an overseas organisation any information that the Regulator—
- (a) holds in relation to the performance or exercise of the Regulator's functions, powers, or duties under this Act; and
 - (b) considers may assist the recipient in the performance or exercise of its functions, powers, or duties.
- (2) A regulatory entity may give to the Regulator any information that the agency—
- (a) holds in relation to the performance or exercise of its functions, powers, or duties; and
 - (b) considers may assist the Regulator in the performance or exercise of its functions, powers, or duties under this Act.
- (3) The Regulator or regulatory entity may give the information subject to any conditions it considers appropriate.
- (4) The Regulator must not give information to an overseas regulator or overseas organisation unless satisfied that appropriate protections will be in place to maintain,—
- (a) if the information is confidential, its confidentiality; and
 - (b) if the information is personal information (as defined in the Privacy Act 1993), the privacy of the person to whom it relates.
- (5) This section applies—

- (a) despite anything to the contrary in any contract, deed, or document;
- (b) subject to **subpart 4 of Part 4**.

210 Power of Regulator to act on requests of overseas regulators, etc

- (1) At the request of an overseas regulator or overseas organisation (the **requesting body**), the Regulator may exercise any of its powers under **subpart 2 of Part 6**, to obtain information or things to assist the requesting body in the performance or exercise of its functions, powers, or duties.
- (2) The Regulator may comply with a request only if satisfied that—
 - (a) compliance will not substantially affect the performance of the Regulator's other functions; and
 - (b) it is otherwise appropriate to do so.
- (3) The Regulator may give any information or things obtained by it to the requesting body.
- (4) However, the Regulator must not give information to the requesting body unless satisfied that appropriate protections will be in place to protect—
 - (a) if the information is confidential, its confidentiality; and
 - (b) if the information is personal information (as defined in the Privacy Act 1993), the privacy of the person to whom it relates.
- (5) For the purpose of the Regulator exercising the powers referred to in **subsection (1)**, assisting the requesting body in the performance or exercise of its functions, powers, or duties is an investigative purpose (*see* **section 183**).

Applications

211 Applications to Regulator

- (1) This section and **sections 212 to 217** apply to any application to the Regulator for the purposes of this Act other than an application for review under **section 200**.
- (2) To make an application to the Regulator, a person must—
 - (a) make the application in the way specified in the rules; and
 - (b) comply with any procedural requirements specified in the rules; and
 - (c) pay the specified fee.

212 Regulator may request further information, site access, etc

- (1) The Regulator may request an applicant to do either or both of the following:
 - (a) give to the Regulator any further information the Regulator reasonably needs to assess the application:

- (b) allow the Regulator (or a person authorised by the Regulator) to inspect any place, equipment, process, document, or other thing that the Regulator reasonably needs to inspect in order to assess the application.
- (2) The Regulator's request must be made in writing and specify a reasonable time within which it must be complied with.
- (3) After making a request, the Regulator may defer consideration of the application until the request is complied with.

213 Regulator may obtain information

For the purpose of assessing an application, the Regulator may obtain any other information the Regulator considers appropriate.

214 Information is part of application

Any information that the applicant gives to the Regulator in relation to the application (whether given with the application, in response to a request under **section 212**, or otherwise) is taken to be part of the application.

215 Regulator may reject non-complying application

The Regulator may reject the application without considering its merits if—

- (a) **section 211** is not complied with; or
- (b) a request made under **section 212** is not complied with in the specified time; or
- (c) the Regulator is satisfied that any information in the application is misleading information.

216 Opportunity to comment before adverse decision

- (1) The Regulator must not make an adverse decision on an application unless the Regulator has given the applicant an opportunity to comment.
- (2) An **adverse decision**, in relation to an application, means a decision to—
 - (a) refuse the application; or
 - (b) grant the application on terms or conditions that are materially more restrictive than those sought by the applicant.

217 Notice of decision

As soon as practicable after making a decision on an application, the Regulator must notify the applicant of the decision.

Notice, service of documents, etc

218 Notification to Regulator

- (1) If a person is required by a provision of this Act to notify the Regulator of a matter, the person must—

- (a) notify the Regulator in the way specified in the rules; and
 - (b) comply with any procedural requirements specified in the rules; and
 - (c) pay the specified fee.
- (2) The Regulator may refuse to accept the notification if **subsection (1)** is not complied with.

219 Meaning of make publicly available

- (1) If the Regulator is required under this Act to **make publicly available** a document or other information, the Regulator must—
- (a) publish it on the Regulator’s Internet site; and
 - (b) ensure that it can be viewed by members of the public on that Internet site at all reasonable times free of charge.
- (2) The Regulator may also publicise it, or make it available, in any other way the Regulator considers appropriate.

220 Service of documents

- (1) If a document is required under this Act to be served on a person (the **addressee**), the document or a copy of it must be served,—
- (a) if the addressee is an individual, in accordance with **subsection (2)**; or
 - (b) if the addressee is a company or an overseas company (as defined in section 2(1) of the Companies Act 1993), in a manner provided for in sections 387 to 390 of that Act; or
 - (c) if the addressee is any other entity, in a manner in which it could be served if it were a company under **paragraph (b)**; or
 - (d) in any other way authorised by a District Court Judge.
- (2) A document may be served on an individual addressee by any of the following methods:
- (a) giving it to the addressee, or if they do not accept it, by putting it in a place accessible to them and bringing it to their attention;
 - (b) leaving it for the addressee at their last known place of residence or work, with an individual who appears to be at least 14 years of age;
 - (c) sending it to the addressee by prepaid post to their last known place of residence or work;
 - (d) if the addressee does not have a known place of residence or work in New Zealand, sending it to the addressee’s email address.
- (3) If a document is being served under **subsection (1)(b) or (c)**, section 392 of the Companies Act 1993 applies.
- (4) If a document is posted under **subsection (2)(c)**, it is to be treated as having been served on the addressee on the 5th working day after the day on which it was posted.

*Miscellaneous***221 Certificate of status for overseas supply of therapeutic product**

- (1) The Regulator may, on application, issue a certificate (a **certificate of product status**) in relation to a medicine, medical device, or type-4 product, certifying—
 - (a) whether it is an approved product or an approval-exempt product; and
 - (b) if not, whether a particular person is authorised to supply the product to a person who is outside New Zealand without it being approved.
- (2) The Regulator may include in the certificate any other information relating to the product that the Regulator considers it appropriate to include.
- (3) A certificate of product status may be issued for an approved product, an approval-exempt product, or an unapproved product that is manufactured in New Zealand.
- (4) A person may apply for a certificate of product status only if the person is,—
 - (a) for an approved product or an approval-exempt product, the product's sponsor; or
 - (b) for an unapproved product manufactured in New Zealand, the responsible manufacturer.

222 Correction of errors

- (1) The Regulator may correct an error or omission that it is satisfied it has made in any of the following:
 - (a) an approval, a licence, or a permit;
 - (b) a register;
 - (c) any other document kept or issued by the Regulator under this Act.
- (2) Before making the correction, the Regulator must give the persons the Regulator thinks have an interest in the matter an opportunity to comment.

Part 7**Enforcement**

Subpart 1—Enforceable undertakings

223 Regulator may accept undertakings

- (1) The Regulator may, on application, accept an undertaking given by a person (**person A**) in connection with an alleged contravention of a provision of this Act.
- (2) Without limiting what an undertaking may relate to, an undertaking may include undertakings to do 1 or more of the following:

- (a) pay compensation to any person:
 - (b) take action to avoid, remedy, or mitigate any actual or likely adverse effects arising from the alleged contravention:
 - (c) take action to—
 - (i) reduce the likelihood of future contraventions:
 - (ii) avoid or mitigate any likely adverse effects arising from future contraventions:
 - (d) pay to the Crown an amount in lieu of proceedings being taken in relation to the alleged contravention.
- (3) Giving an undertaking is not an admission of guilt in relation to the alleged contravention.
- (4) However, the Regulator cannot accept an undertaking if the Regulator believes that—
- (a) person A knew that the conduct constituting the alleged contravention was unlawful; and
 - (b) person A engaged in their conduct in relation to the alleged contravention maliciously or with the intention of person A or another person making a gain or avoiding a loss.

224 Undertakings to be made publicly available

If it accepts an undertaking, the Regulator must make the following publicly available:

- (a) the undertaking:
- (b) the Regulator's reasons for accepting it:
- (c) if the undertaking is varied,—
 - (i) the variation; and
 - (ii) the Regulator's reasons for accepting it:
- (d) when the undertaking ceases to be in force, notice of—
 - (i) whether it expired or was complied with, was withdrawn, or was discharged; and
 - (ii) the date it ceased to be in force.

225 When undertaking is in force

- (1) An undertaking takes effect and becomes enforceable when notice of the Regulator's decision to accept the undertaking is given under **section 217**, or on any later date specified in it.
- (2) An undertaking remains in force until—
 - (a) it expires or is complied with according to its terms; or
 - (b) it is withdrawn under **section 226**; or

- (c) it is discharged by a court.

226 Withdrawal of enforceable undertaking

A person who has given an enforceable undertaking may withdraw it by notifying the Regulator.

227 Variation of enforceable undertaking

- (1) The Regulator may, on application by a person who has given an enforceable undertaking, accept a variation of the undertaking.
- (2) However, the undertaking cannot be varied so as to relate to a different contravention of this Act.

228 Compliance with enforceable undertaking

- (1) A person who has given an enforceable undertaking must comply with it.
- (2) If a person contravenes **subsection (1)**,—
 - (a) if they do so wilfully, they commit a level B1 offence; or
 - (b) if they do so recklessly, they commit a level B2 offence; or
 - (c) otherwise, they commit a level B3 offence.
- (3) A person who commits an offence under **subsection (2)** is liable on conviction to the appropriate penalty set out in **section 233**.

229 Contravention of enforceable undertaking

- (1) The District Court may, on application by the Regulator, make an order under this section if it is satisfied that a person who gave an enforceable undertaking has not complied with it.
- (2) An order under this section may do 1 or more of the following:
 - (a) direct the person to comply with the undertaking;
 - (b) discharge the undertaking;
 - (c) direct the person to pay to the Regulator—
 - (i) the costs of the proceedings; and
 - (ii) the reasonable costs of the Regulator in monitoring compliance with the undertaking (including in the future).
- (3) This section does not prevent proceedings being brought in relation to the alleged contravention to which the enforceable undertaking relates.

230 Proceedings for alleged contravention

- (1) If a person has given an enforceable undertaking in relation to an alleged contravention, no proceedings (whether civil or criminal) may be brought against that person for the alleged contravention—
 - (a) while the undertaking is in force; or

- (b) at any later time, if the person who gave the undertaking has completely complied with it.
- (2) If the Regulator accepts an undertaking in relation to an alleged contravention after proceedings for that contravention have been commenced but before they are completed, the Regulator must discontinue the proceedings as soon as practicable.

231 Limitation period for proceedings after undertaking contravened or withdrawn

- (1) This section applies if—
 - (a) a person has given an enforceable undertaking in relation to an alleged contravention; and
 - (b) the person—
 - (i) contravenes the undertaking; or
 - (ii) withdraws the undertaking; and
 - (c) the alleged contravention is an offence; and
 - (d) the time allowed under section 25 of the Criminal Procedure Act 2011 for filing a charging document in relation to that offence—
 - (i) expired on or before the relevant date; or
 - (ii) will expire not more than 6 months after the relevant date.
- (2) If this section applies, then, despite section 25 of the Criminal Procedure Act 2011, proceedings for the offence may be brought within 6 months after the relevant date.
- (3) In this section, **relevant date** means the date on which—
 - (a) the contravention of the enforceable undertaking comes to the notice of the Regulator; or
 - (b) the undertaking is withdrawn under **section 226**.

Subpart 2—Injunctions

232 Court may grant injunction

- (1) A court may, on application, grant an injunction restraining a person from engaging in conduct that would contravene a provision of this Act.
- (2) The court may grant an injunction restraining a person from engaging in conduct of a particular kind if it is satisfied that—
 - (a) the person has engaged in conduct of that kind; or
 - (b) it is likely that the person will engage in conduct of that kind if an injunction is not granted.
- (3) The court may grant an interim injunction restraining a person from engaging in conduct of a particular kind if it appears to the court desirable to do so.

- (4) **Subsections (2)(a) and (3)** apply whether or not the person intends to engage again, or to continue to engage, in conduct of that kind.
- (5) **Subsections (2)(b) and (3)** apply whether or not the person has previously engaged in conduct of that kind or there is an imminent danger of substantial damage to any other person if that person engages in conduct of that kind.
- (6) An application for an injunction may be made only by the Regulator.
- (7) On an application for an interim injunction, the court—
 - (a) must not make the grant of the injunction conditional on the Regulator giving an undertaking as to damages; and
 - (b) in deciding whether to grant the injunction, must not take into account the fact that the Regulator is not required to give an undertaking as to damages.

Subpart 3—Offences

Penalties

233 Penalties for offences

- (1) A person who commits a level A1 offence is liable on conviction to,—
 - (a) for an individual, imprisonment for a term not exceeding 5 years and a fine not exceeding \$200,000; or
 - (b) otherwise, a fine not exceeding \$1,000,000.
- (2) A person who commits a level A2 offence is liable on conviction to,—
 - (a) for an individual, a fine not exceeding \$100,000; or
 - (b) otherwise, a fine not exceeding \$500,000.
- (3) A person who commits a level A3 offence is liable on conviction to,—
 - (a) for an individual, a fine not exceeding \$70,000; or
 - (b) otherwise, a fine not exceeding \$300,000.
- (4) A person who commits a level B1 offence is liable on conviction to,—
 - (a) for an individual, a fine not exceeding \$100,000; or
 - (b) otherwise, a fine not exceeding \$500,000.
- (5) A person who commits a level B2 offence is liable on conviction to,—
 - (a) for an individual, a fine not exceeding \$50,000; or
 - (b) otherwise, a fine not exceeding \$250,000.
- (6) A person who commits a level B3 offence is liable on conviction to,—
 - (a) for an individual, a fine not exceeding \$30,000; or
 - (b) otherwise, a fine not exceeding \$170,000.

*Other orders available to court***234 When court may make other orders**

- (1) A court sentencing a defendant for an offence against this Act may make an order against the defendant under 1 or more of **sections 235 to 237**.
- (2) The order may be made instead of, or in addition to, any other penalty that may be imposed on the defendant.

235 Suspension or cancellation of licence or permit

- (1) This section applies if the defendant—
 - (a) is a licensee or permit holder; or
 - (b) is a senior manager of a licensee or permit holder against whom the proceedings were brought in reliance on **section 242**.
- (2) The court may, by order, cancel or suspend the licence or permit if satisfied that grounds exist to suspend or cancel the licence or permit (as defined in **section 141 or 142**).
- (3) Before doing so, the court must give the Regulator an opportunity to make submissions on the matter to the court.

236 Cancellation of approval

- (1) This section applies if the defendant—
 - (a) is the sponsor of an approved product; or
 - (b) is a senior manager of a sponsor of an approved product against whom the proceedings were brought in reliance on **section 242**.
- (2) The court may, by order, cancel the approval if satisfied that grounds exist to cancel the approval (as defined in **section 108**).
- (3) Before doing so, the court must give the Regulator an opportunity to make submissions on the matter to the court.

237 Order to pay Regulator's expenses of mitigating risk harm

- (1) This section applies if—
 - (a) the defendant is being sentenced for a level A1, A2, or A3 offence; and
 - (b) the defendant's conduct caused harm or a risk of harm; and
 - (c) the Regulator has incurred costs or expenses to mitigate that risk.
- (2) The court may order the defendant to pay to the Regulator an amount not exceeding those costs or expenses.
- (3) For the purposes of this section, conduct **causes harm or a risk of harm** if the conduct—
 - (a) directly or indirectly—
 - (i) causes harm; or

- (ii) significantly increases harm; or
- (iii) creates a significant risk of harm; or
- (iv) significantly increases a risk of harm; or
- (b) might reasonably be expected to do something referred to in **paragraph (a)**.

Notification

238 Notice of court orders

- (1) If a court makes an order under **section 235 or 236**, the court Registrar must give a copy of the order to the Regulator as soon as practicable after it is made.
- (2) If a court convicts a health practitioner or veterinarian of an offence against this Act, the court Registrar must notify,—
 - (a) for a health practitioner, the authority for the practitioner’s profession under the Health Practitioners Competence Assurance Act 2003; or
 - (b) for a veterinarian, the Veterinary Council of New Zealand under the Veterinarians Act 2005.

Subpart 4—Attribution of liability and defences

Attribution of liability

239 Conduct of senior managers, workers, and agents attributed upwards

- (1) If a person (**person A**)—
 - (a) is a senior manager, a worker, or an agent of another person (**person B**); and
 - (b) engages in conduct on behalf of person B; and
 - (c) in doing so is acting within the scope of person A’s actual or apparent authority,—
 then person B is taken to have also engaged in the conduct.
- (2) If the conduct contravenes a provision of this Act, this section applies whether or not proceedings are taken against person A for the contravention.
- (3) However, in a prosecution of person B for the contravention in reliance on **subsection (1)**, it is a defence if person B—
 - (a) did not know, and could not reasonably be expected to have known, of the contravention; and
 - (b) took all reasonable steps to ensure the contravention was not committed.

240 Authorisation for attributed conduct

- (1) This section applies if—
 - (a) a person (**person A**) is—

-
- (i) a senior manager, a worker, or an agent of another person (**person B**); and
 - (ii) is authorised to engage in regulated conduct; and
 - (b) person A engages in that conduct; and
 - (c) under **section 239**, person A's conduct is attributed to person B; and
 - (d) person B is not authorised (other than by this section) to engage in that conduct.
- (2) If this section applies, person A's authorisation to engage in that conduct is taken to also authorise person B.
- (3) To avoid doubt, person B's authorisation under this section—
- (a) only authorises person B in relation to conduct of person A that is attributed to person B under **section 239**; and
 - (b) does not authorise person B to engage in that conduct themselves or through any other senior manager, worker, or agent.

- (4) In this section,—

authorised means authorised by a licence, permit, or provision of **subpart 3 of Part 3**

regulated conduct means conduct that is unlawful under this Act unless the person engaging in it is authorised to do so.

241 State of mind of senior managers, workers, or agents attributed upwards

- (1) This section applies in proceedings under this Act if—
- (a) the proceedings relate to conduct engaged in by a person (**person A**); and
 - (b) it is necessary to establish the state of mind of person A.
- (2) It is sufficient to show that a senior manager, a worker, or an agent of person A, acting within the scope of their actual or apparent authority, had that state of mind.
- (3) However, **subsection (2)** does not apply if—
- (a) person A is an individual; and
 - (b) the proceedings are criminal proceedings.

242 Contravention of body corporate attributed downward to senior managers

- (1) If—
- (a) a body corporate (**company A**) contravenes a provision of this Act; and
 - (b) another person (**person B**) was a senior manager of company A at the time of the contravention,—
- then person B is taken to have also contravened that provision.

- (2) This section applies whether or not proceedings are taken against company A for the contravention.
- (3) However, in a prosecution of person B for an offence for the contravention in reliance on **subsection (1)**, it is a defence if person B—
 - (a) did not know, and could not reasonably be expected to have known, of the contravention; and
 - (b) took all reasonable steps to ensure the contravention was not committed.

Defences

243 All reasonable steps

In a prosecution for an offence against a provision of this Act (other than **section 85, 89, or 91**), it is a defence if the defendant took all reasonable steps to ensure the contravention was not committed.

244 Reasonable excuse

- (1) In a prosecution for an offence of contravening **section 51(1), 52(1), 53(1), 54(1), 81(1), 83(1), 92(1), 174(2), 197(1), or 199(1)**, it is a defence if the defendant has a reasonable excuse for engaging in the conduct that constituted the contravention.
- (2) However, for a contravention that occurs in relation to a therapeutic product, this section does not apply if the defendant is the sponsor of, or a person in the supply chain for, that product.

245 Reliance on information from another person

- (1) In a prosecution for an offence of contravening a provision of this Act, it is a defence if—
 - (a) the contravention was due to the defendant's reliance on information given to the defendant by another person; and
 - (b) the other person was not a senior manager, a worker, or an agent of the defendant; and
 - (c) in the circumstances, it was reasonable for the defendant to rely on that information.
- (2) A person cannot rely on this defence unless—
 - (a) they notify the prosecutor of the identity of the other person referred to in that section at least 7 days before the date on which the hearing of the proceeding is to commence; or
 - (b) the court gives them leave to rely on the defence without complying with **paragraph (a)**.

246 Compliance with specified standard

- (1) This section applies if—

- (a) a provision of this Act requires a person to comply with a requirement that is specified in the regulations; and
 - (b) the regulations specifying the requirement—
 - (i) state that this section applies in relation to that requirement; and
 - (ii) specify a compliance standard for that requirement.
- (2) In a prosecution for an offence of contravening that provision, it is a defence if the conduct that is alleged to contravene the provision complied with the compliance standard.

Subpart 5—Evidentiary matters

247 **Presumption that contents are as labelled**

In proceedings under this Act, it must be presumed that the contents of a container conform with any purported description of the contents shown on any label attached to the container unless the contrary is proved.

248 **Evidence of testing**

- (1) In proceedings under this Act, a certificate of testing issued by an analyst is proof of the matters set out in it unless the contrary is proved.
- (2) However, a certificate is admissible in evidence only if,—
 - (a) at least 10 working days before the hearing at which the certificate is given in evidence, a copy of the certificate (in addition to any copy served with any summons) is served by the prosecutor; and
 - (b) at the same time, the defendant is informed in writing that the prosecutor does not propose to call the person who did the testing as a witness at the hearing; and
 - (c) the defendant does not, by notice in writing to the prosecutor at least 5 working days before the hearing, require the person who did the testing to be called by the prosecutor as a witness at the hearing.
- (3) A certificate is not admissible in evidence if a court, of its own motion, directs that the result of the testing must be disregarded unless the result is proved by the oral evidence of the person who did the testing.

Subpart 6—Infringement offences

249 **Meaning of infringement circumstances and infringement offence**

- (1) The **infringement circumstances** for a provision of this Act are any circumstances specified in the regulations as circumstances in which a contravention of that provision is an infringement offence.
- (2) An **infringement offence** is a contravention of a provision of this Act that is stated to be an infringement offence (because it occurs in infringement circumstances).

250 Meaning of infringement fee and infringement fine

- (1) In this Act,—
- infringement fee**, for an infringement offence, means the amount specified in the regulations as the infringement fee for that infringement offence
- infringement fine**, for an infringement offence, means the amount specified in the regulations as the maximum fine that could be imposed under section 375(1)(b) of the Criminal Procedure Act 2011 for that infringement offence.
- (2) The regulations must specify the infringement fee and infringement fine for each infringement offence.
- (3) In regulations for the purposes of **subsection (2)**, in relation to an infringement offence involving the contravention of a provision of this Act,—
- (a) the infringement fine must not be more than the bottom tier criminal fine for the provision; and
- (b) the infringement fee must not be more than 5% of the bottom tier criminal fine.
- (4) All infringement fees received by the Regulator must be paid into a Crown Bank Account.
- (5) In this section, **bottom tier criminal fine**, for a provision of this Act, means the maximum fine that a court could impose for the level A3 or B3 offence (as applicable) for a contravention of that provision if it occurred in circumstances that were not infringement circumstances.

251 Penalty for infringement offence

A person who commits an infringement offence is liable,—

- (a) under an infringement notice, to the infringement fee for the infringement offence; or
- (b) if fined under section 375(1)(b) of the Criminal Procedure Act 2011, to a fine not exceeding the infringement fine for the infringement offence.

252 How infringement offences may be dealt with

- (1) If a person is alleged to have committed an infringement offence—
- (a) an infringement notice may be issued to the person under **section 253**; or
- (b) criminal proceedings may be commenced against the person under section 14 of the Criminal Procedure Act 2011.
- (2) The criminal proceedings may be commenced without the leave of a District Court Judge or Registrar despite section 21(1)(a) of the Summary Proceedings Act 1957.

253 Regulator may issue infringement notice

- (1) If the Regulator believes that the person has committed an infringement offence, the Regulator may—
 - (a) issue an infringement notice for the infringement offence; and
 - (b) serve the infringement notice on the person in accordance with **section 220**.
- (2) The infringement notice must be served on the person not more than 6 months after the date on which the infringement offence was committed.

254 Form and content of infringement notice and reminder notice

- (1) An infringement notice for an infringement offence—
 - (a) must be in the form specified in the regulations; and
 - (b) must contain the following information:
 - (i) details of the offence, expressed in a way that fairly informs the recipient of the notice of the nature of the offence and where and when it occurred;
 - (ii) the infringement fee;
 - (iii) when the infringement fee must be paid;
 - (iv) the maximum fine that could be imposed under section 375(1)(b) of the Criminal Procedure Act 2011;
 - (v) any other information specified by the regulations.
- (2) A reminder notice—
 - (a) must be in the form specified in the regulations; and
 - (b) must contain substantially the same information as the infringement notice it relates to.
- (3) The form of infringement notice or reminder notice specified in the regulations must include the following:
 - (a) details of how an infringement fee may be paid;
 - (b) a summary of the effect of section 21(10) of the Summary Proceedings Act 1957;
 - (c) a statement that the recipient of an infringement notice has a right to request a hearing;
 - (d) a statement of what will happen if the recipient does not pay the infringement fee or request a hearing within the time allowed.

255 Infringement notice may be revoked

- (1) The Regulator may revoke an infringement notice by notifying the recipient of the infringement notice.
- (2) The Regulator cannot do so if—

- (a) the infringement fee has been paid; or
- (b) an order has been made under section 21 of the Summary Proceedings Act 1957.

Part 8

Administrative matters

Subpart 1—Cost recovery

256 Costs to be recovered

- (1) The Regulator must take all reasonable steps to ensure that the direct and indirect costs of administering this Act that are not provided for by money appropriated by Parliament for that purpose are recovered by way of fees or charges specified in the regulations.
- (2) The Regulator must review the methods and levels of cost recovery at least once every 3 years.
- (3) The Regulator must make the results of each review publicly available.
- (4) If a fee or charge is payable in relation to the performance of a function or exercise of a power by the Regulator, the Regulator may refuse to perform the function or exercise the power until the fee or charge is paid.
- (5) Fees and charges payable under this Act are a debt due to the Crown and may be recovered by the Regulator (on behalf of Crown).

257 Regulations about fees and charges

- (1) The regulations may specify fees and charges for the purposes of this Act.
- (2) The regulations may specify any of the following—
 - (a) the amount of fees or charges or the methods by which they are to be calculated;
 - (b) the persons liable to pay the fees or charges;
 - (c) when the fees or charges must be paid;
 - (d) how fees and charges may be recovered;
 - (e) circumstances in which the fees or charges may be refunded, remitted, or waived (wholly or partly).

Subpart 2—Regulations, rules, Regulator’s notices, and exemptions

258 Types of secondary legislation and instruments

This subpart provides for the following to be made for the purposes of this Act:

- (a) regulations made under **section 261**;
- (b) rules made under **section 262**;

- (c) Regulator's notices made under **section 263**;
- (d) exemptions made under **section 264**.

259 Interaction between types of secondary legislation and instruments

- (1) If the regulations are inconsistent with the rules or a Regulator's notice, the regulations prevail to the extent of the inconsistency.
- (2) If the rules are inconsistent with a Regulator's notice, the rules prevail to the extent of the inconsistency.

260 Application of Legislation Act 2012

- (1) This section applies for the purposes of the Legislation Act 2012.
- (2) The regulations, rules, and any exemption—
 - (a) are legislative instruments and disallowable instruments; and
 - (b) must be presented to the House of Representatives under section 41 of that Act.
- (3) A Regulator's notice—
 - (a) is not a legislative instrument or a disallowable instrument; and
 - (b) does not have to be presented to the House of Representatives under section 41 of that Act.

261 Regulations

The Governor-General may, by Order in Council, make regulations—

- (a) to specify 1 or more of the matters listed in **clause 1 of Schedule 3**;
or
- (b) to provide for any other matters contemplated by this Act, necessary for its administration, or necessary for giving effect to this Act.

262 Rules

The Regulator may make rules to specify 1 or more of the matters listed in **clause 2 of Schedule 3**.

263 Regulator's notices

- (1) The Regulator may make notices under this section to specify—
 - (a) 1 or more of the matters listed in **clause 3 of Schedule 3**; or
 - (b) any matter that the regulations authorise to be done by Regulator's notice under **section 265(2)**.
- (2) However, the Regulator must not make a Regulator's notice unless satisfied that doing so—
 - (a) is necessary or desirable in order to promote the purpose of this Act; and
 - (b) is consistent with the principles set out in **section 4**.

- (3) After making a Regulator's notice, the Regulator must make publicly available—
 - (a) the notice; and
 - (b) a statement of the Regulator's reasons for making the notice (including why it is necessary or desirable).
- (4) A Regulator's notice must specify in it the date on which it comes into force (which cannot be before it is made publicly available under **subsection (3)**).
- (5) A Regulator's notice—
 - (a) comes into force at the beginning of the date specified in it; and
 - (b) remains in force,—
 - (i) if it has an expiry date, until the close of that date (unless it is revoked before then); or
 - (ii) otherwise, until it is revoked.

264 Exemptions

- (1) The Regulator may exempt 1 or more of the following from a provision of this Act:
 - (a) an act or a thing or a class of acts or things;
 - (b) a class of persons.
- (2) However, the Regulator must not do so unless satisfied that—
 - (a) granting the exemption—
 - (i) is necessary or desirable in order to promote the purpose of this Act; and
 - (ii) is consistent with the principles set out in **section 4**; and
 - (b) the extent of the exemption is not broader than is reasonably necessary to address the matters that gave rise to the exemption.
- (3) An exemption must specify in it—
 - (a) the date on which it comes into force (which cannot be before it is published under the Legislation Act 2012); and
 - (b) the date on which it expires (which cannot be more than 5 years after it comes into force).
- (4) An exemption—
 - (a) comes into force at the beginning of the date specified in it; and
 - (b) remains in force until the close of the specified expiry date, when it is revoked (unless it is revoked by the Regulator before then).

265 Scope of regulations, rules, Regulator's notices, and exemptions

- (1) The regulations or rules, or a Regulator's notice or an exemption, may,—

- (a) specify persons, acts, matters, or things individually or by class (subject to **section 264(1)(b)**):
 - (b) make different provision for different cases on any differential basis:
 - (c) make provision for things either unconditionally or subject to conditions:
 - (d) provide that a requirement that applies in relation to approved products may be disapplied for a particular product by the product's approval:
 - (e) provide that a requirement that applies in relation to licences or permits may be disapplied for a particular licence or permit by the licence or permit:
 - (f) confer a discretion on, or allow a matter to be determined or approved by, the Regulator or another person.
- (2) The regulations or rules may provide for things of an administrative nature to be done by the Regulator by Regulator's notice.
- (3) The regulations may—
- (a) provide for a contravention of the regulations to be—
 - (i) an offence, if it occurs in circumstances that are not infringement circumstances:
 - (ii) an infringement offence, if it occurs in infringement circumstances:
 - (b) specify fines for offences referred to in **paragraph (a)(i)** not exceeding,—
 - (i) for an individual, \$30,000; or
 - (ii) otherwise, \$170,000.

266 Incorporation by reference

[Note for consultation draft: Under the Legislation Act 2012, the regulations, rules, and any exemptions made under this Bill will be able to incorporate material by reference in accordance with subpart 2 of Part 3 of that Act.

The Legislation Act 2012 is expected to be replaced by the Legislation Bill that is currently before Parliament. The Legislation Bill will continue the ability for the regulations, rules, and exemptions to incorporate material by reference.

It is intended to include provisions in this Bill to allow Regulator's notices to also incorporate material by reference in a way that mirrors, as far as practicable, the process applying to secondary legislation under the Legislation Bill. These provisions are being developed in conjunction with the Legislation Bill and Parliamentary Counsel Office's Access to Secondary Legislation Project and are not yet available.]

267 Consultation

- (1) The Minister must not recommend the making of regulations without first consulting persons and organisations that the Minister considers appropriate, having regard to the subject matter of the proposed regulations.
- (2) The Regulator must not make rules, a Regulator's notice, or an exemption without first consulting persons and organisations that the regulator considers appropriate, having regard to the subject matter of the proposed rules, notice, or exemption.
- (3) However, a failure to comply with this section does not affect the validity of the regulations, rules, notice, or exemption.

Subpart 3—Review of Act**268 Minister must review Act**

- (1) The Minister must conduct a review of the policy and operation of this Act after the expiry of—
 - (a) 5 years from the commencement of this Act; and
 - (b) each subsequent period of 5 years.
- (2) The Minister must—
 - (a) prepare a report on the review within 12 months after the end of the 5-year period to which it relates; and
 - (b) present the report to the House of Representatives as soon as practicable after it is completed.

Subpart 4—Relationship with other Acts**269 Relationship with Food Act 2014**

- (1) The Food Act 2014 regulates food, which is defined as anything that is used, capable of being used, or represented as being for use, for human consumption (*see* section 9 of that Act).
- (2) However, various things are excluded from that definition, including therapeutic products. Therefore, if a product is a therapeutic product, it is not food for the purposes of the Food Act 2014 even if it could be eaten.
- (3) Some substances can be used to make both therapeutic products and food. Whether a product that is made of, or contains, such a substance is a therapeutic product depends on whether the particular product (not the substance) falls within the definition of therapeutic product in **section 16** of this Act.

Example

Salt can be found in both therapeutic products and food. If salt tablets were manufactured and marketed for medicinal purposes, they would be a therapeutic product and not food. But table salt, manufactured and marketed as food seasoning,

would be food and not a therapeutic product. This is so even if they contain the same ingredients.

- (4) In a few cases, a product that is a therapeutic product may also be used for human consumption. If so, and if it is decided that it would be more appropriate for it to be regulated under the Food Act 2014 than this Act, regulations could be made for the purposes of **section 16(4)** to declare it not to be a therapeutic product. It would then be caught by the definition of food in the Food Act 2014.

270 Relationship with Hazardous Substances and New Organisms Act 1996

- (1) The HSNO Act prohibits the importation or manufacture of a hazardous substance, or the importation, development, field testing, or release of a new organism, without an approval granted under that Act.
- (2) A therapeutic product may be, or contain, a hazardous substance or a new organism. If that is the case, both this Act and the HSNO Act apply to it.
- (3) If both Acts apply to a product,—
 - (a) an approval under the HSNO Act is effective only for the purposes of that Act and does not authorise a person to do something that is unlawful under this Act; and
 - (b) an approval, licence, permit, or other authorisation under this Act is effective only for the purpose of this Act and is not an approval for the purpose of the HSNO Act.

- (4) In this section,—

hazardous substance has the same meaning as in section 2(1) of the HSNO Act

HSNO Act means the Hazardous Substances and New Organisms Act 1996

new organism has the same meaning as in section 2(1) of the HSNO Act.

271 Relationship with Human Tissue Act 2008

- (1) Human tissue may be, or be part of, a therapeutic product. If that is the case, both this Act and the Human Tissue Act 2008 apply to it.
- (2) The Human Tissue Act 2008 regulates the collection and use of human tissue.
- (3) For the purposes of that Act, use of human tissue includes—
 - (a) use in the development, making or preparation, and testing of therapeutic products; and
 - (b) use in the carrying out of a health-care procedure (if the tissue is not a therapeutic product).
- (4) The Human Tissue Act 2008 prohibits trade in human organs. This prohibition is not changed by this Act.

272 Relationship with Misuse of Drugs Act 1975

If a therapeutic product is or contains a controlled drug, both this Act and the Misuse of Drugs Act 1975 apply in relation to it.

[Note for consultation draft: These provisions are being developed in conjunction with the consequential amendments that will need to be made to the Misuse of Drugs Act 1975 in order to reflect the move from the Medicines Act 1981 to this Bill. They are therefore not included in this consultation draft of the Bill.]

273 Relationship with Psychoactive Substances Act 2013

- (1) The Psychoactive Substances Act 2013 regulates substances, mixtures, preparations, articles, devices, and things that are capable of inducing a psychoactive effect.
- (2) However, if something that is capable of having a psychoactive effect is also a therapeutic product,—
 - (a) this Act applies to it; and
 - (b) the Psychoactive Substances Act 2013 does not apply to it (*see* section 9(3)(c) of that Act).

274 Relationship with Radiation Safety Act 2016

- (1) The Radiation Safety Act 2016 regulates the use of radioactive material and irradiating apparatus.
- (2) If something is both a therapeutic product and radioactive material or irradiating apparatus, then both this Act and the Radiation Safety Act 2016 apply to it.

Part 9

Repeals, revocations, and amendments to other enactments

Subpart 1—Repeals and revocations

275 Repeals and revocations

- (1) The Medicines Act 1981 (1981 No 118) is repealed.
- (2) The following regulations are revoked:
 - (a) Medicines Regulations 1984 (SR 1984/143):
 - (b) Medicines (Database of Medical Devices) Regulations 2003 (SR 2003/325):
 - (c) Medicines (Designated Pharmacist Prescribers) Regulations 2013 (SR 2013/237):
 - (d) Medicines (Designated Prescriber—Dietitians) Regulations 2015 (LI 2015/149):

- (e) Medicines (Designated Prescriber—Registered Nurses) Regulations 2016 (LI 2016/140):
 - (f) Medicines (Related Products (Exempted Foods)) Regulations 2003 (SR 2003/371):
 - (g) Medicines (Standing Order) Regulations 2002 (SR 2002/373).
- (3) The Medicines (Approved Laboratories and Analysts in Charge) Notice 2000 (SR 2000/173) is revoked.

Subpart 2—Amendments to Health Practitioners Competence Assurance Act 2003

276 Amendments to Health Practitioners Competence Assurance Act 2003

This subpart amends the Health Practitioners Competence Assurance Act 2003. *These amendments to the Health Practitioners Competence Assurance Act 2003 are drafted on the assumption that the Health Practitioners Competence Assurance Amendment Bill, which is currently before Parliament, will be passed and come into force before this Bill. The only relevance of that Bill to these amendments is that it affects some of the section numbering and will insert a new Schedule IAA into the Act. Notes have been included below to explain the impact of this where it is relevant.*

277 Section 5 amended (Interpretation)

In section 5(1), insert in their appropriate alphabetical order:

medicinal product means a medicine, as defined in **section 18** of the Therapeutic Products Act **2018**

prescribe, in relation to a medicinal product, has the same meaning as in **section 38** of the Therapeutic Products Act **2018**

standing order has the same meaning as in **section 40** of the Therapeutic Products Act **2018**

278 Section 11 amended (Authorities must specify scopes of practice)

After section 11(2), insert:

- (3) This section is subject to **section 11A(2)**.

279 New section 11A inserted (Scope of practice may include prescribing of medicinal products and issuing of standing orders)

After section 11, insert:

11A Scope of practice may include prescribing of medicinal products and issuing of standing orders

- (1) A scope of practice—

- (a) may include the prescribing of 1 or more medicinal products or classes of medicinal products; and
 - (b) if so, may also include the issuing of standing orders for 1 or more of those medicinal products.
- (2) However, the responsible authority must not publish the scope of practice under section 11 unless—
- (a) the scope of practice complies with any requirements relating to the form and content of the prescribing provisions prescribed by the regulations; and
 - (b) the Minister has approved the prescribing provisions.
- (3) The prescribing of medicinal products or issuing of standing orders may be included in a scope of practice subject to any conditions the responsible authority thinks fit.
- (4) Conditions under **subsection (3)** may (without limitation) relate to any of the following:
- (a) the qualifications or experience of practitioners who may prescribe a medicinal product or issue a standing order;
 - (b) the circumstances in which a practitioner may, or must not, prescribe a medicinal product or issue a standing order.
- (5) If the scope of practice includes conditions under **subsection (4)(a)**, sections 12(2) to (4) and 13 apply with any necessary modifications.
- (6) In exercising a power under this section, the Minister must be guided by the purpose and principles set out in **sections 3 and 4** of the Therapeutic Products Act **2018**.
- (7) In this section, **prescribing provisions** means any part of the scope of practice that relates to the prescribing of a medicinal product or the issuing of a standing order, including provisions setting out—
- (a) the medicinal products or classes of medicinal products that may be prescribed; and
 - (b) the medicinal products or classes of medicinal products for which standing orders may be issued; and
 - (c) any conditions referred to in **subsection (3)**.

280 Section 14 amended (Provisions relating to notices under sections 11 and 12)

In section 14(1), replace “An” with “Subject to **section 14A**, an”.

281 New sections 14A and 14B inserted

After section 14, insert:

14A Amendment of scope of practice that includes prescribing of medicinal products

- (1) This section applies in relation to a scope of practice that includes the prescribing of medicinal products.
- (2) The responsible authority must not amend the prescribing provisions (as defined in **section 11A**) unless—
 - (a) the amendments comply with the requirements referred to in **section 11A(2)**; and
 - (b) the Minister has approved the amendments.
- (3) The Minister may direct the responsible authority to amend the scope of practice to revoke or amend the prescribing provisions.
- (4) Before giving a direction under **subsection (3)**, the Minister must give the responsible authority a reasonable opportunity to show why the scope of practice should not be changed (including allowing the authority a reasonable time to consult the persons referred to in section 14(2)(a) and (b)).
- (5) If the Minister gives a direction under **subsection (3)**,—
 - (a) the responsible authority must comply with the direction within the time specified in it; and
 - (b) if the authority does not do so, the Minister may exercise the authority's powers under section 14(1) and amend the scope of practice in accordance with the direction.
- (6) Section 14(2) does not apply to an amendment to a scope of practice made under **subsection (5)**.
- (7) In exercising a power under this section, the Minister must be guided by the purpose and principles set out in **sections 3 and 4** of the Therapeutic Products Act **2018**.

14B Minister's powers under sections 11A and 14A

- (1) In exercising a power under **section 11A or 14A**, the Minister must be guided by the purpose and principles set out in **sections 3 and 4** of the Therapeutic Products Act **2018**.
- (2) The Minister may delegate any of his or her powers under **section 11A or 14A** to the Regulator (as defined in **section 14** of the Therapeutic Products Act **2018**).
- (3) The power of the Minister to delegate under this section—
 - (a) is subject to any prohibitions, restrictions, or conditions contained in this or any other Act in relation to the delegation of the Minister's functions or powers; but
 - (b) does not limit any other power of delegation conferred on the Minister by this or any other Act.

282 Section 67 amended (Notification of convictions)

Replace section 67(b)(ix) with:

- (ix) the Therapeutic Products Act **2018**; or

283 Section 100 amended (Grounds on which health practitioner may be disciplined)

Replace section 100(2)(a)(ix) with:

- (ix) the Therapeutic Products Act **2018**; or

284 Section 170 amended (Regulations)

[Note for consultation draft: section 170(ca) will be inserted by the Health Practitioners Competence Assurance Amendment Bill that is currently before Parliament.]

After section 170(ca), insert:

- (cb) prescribing requirements relating to the form and content of the prescribing provisions (as defined in **section 11A**) of a scope of practice that includes the prescribing of medicinal products:

285 Schedule 1AA amended (Transitional, savings, and related provisions)

[Note for consultation draft: Schedule 1AA, consisting of Part 1, clauses 1 to 4, will be inserted by the Health Practitioners Competence Assurance Amendment Bill that is currently before Parliament.]

In Schedule 1AA, after clause 4, insert:

Part 2

Provision relating to Therapeutic Products Act 2018

5 Updating of scopes of practice to include prescribing of medicinal products: consultation requirements

- (1) This clause applies if,—
- (a) immediately before the commencement day, some or all health practitioners in a profession were permitted under the Medicines Act 1981 to prescribe medicines (within the meaning of that Act); and
 - (b) the authority for that profession proposes to make or amend a notice under section 11 or 12 so that, after the commencement day, 1 or more of the profession's scopes of practice will include the prescribing of medicinal products (as permitted by **section 11A**).
- (2) To the extent that the proposed notice or amendment relates to the proposed new prescribing regime for the profession, the authority is not required to consult under section 14(2) if the Minister is satisfied that—

- (a) the proposed new prescribing regime for the profession is not materially different from the profession's old prescribing regime; or
- (b) if the proposed new prescribing regime is materially different from the profession's old prescribing regime, the authority has adequately consulted the persons referred to in section 14(2) about the difference.
- (3) To the extent that the proposed notice or amendment relates to anything other than the profession's new prescribing regime, the authority must consult in accordance with section 14(2).
- (4) In this section,—
- commencement day** means the day on which **section 53** of the Therapeutic Products Act **2018** comes into force
- new prescribing regime**, for a profession, means the ability of health practitioners in that profession to prescribe medicinal products and issue standing orders under the Therapeutic Products Act **2018** on and after the commencement date
- old prescribing regime**, for a profession, means the ability of health practitioners in that profession to prescribe medicines and issue standing orders under the Medicines Act 1981 immediately before the commencement date.

Subpart 3—Amendments to Search and Surveillance Act 2012

286 Amendment to Search and Surveillance Act 2012

This subpart amends the Search and Surveillance Act 2012.

287 Schedule amended

In the Schedule, insert in the appropriate alphabetical order:

Therapeutic Products Act 2018	189	Entry and inspection without warrant	All (except subpart 3 and sections 118 and 119 and subpart 8)
	191	Entry and inspection with warrant	All (except sections 118 and 119 and subpart 8)

Subpart 4—Amendment to Customs and Excise Act 2018

288 Amendment to Customs and Excise Act 2018

This subpart amends the Customs and Excise Act 2018.

289 Section 242 amended (Power to seize and detain risk goods or goods involved in certain offences, etc)

Replace section 242(1)(b)(v) with:

- (v) **sections 51, 52, 53, 55, 81, or 171** of the Therapeutic Products Act **2018**:

Subpart 5—Amendments to other enactments

290 Amendments to other enactments

*[Note for consultation draft: The enactments listed in **Schedule 4** have been identified as likely to require amendment as a consequence of this Bill. Those amendments have not yet been drafted.]*

Schedule 1
Transitional, savings, and related provisions

s 5

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Part 1

Transitional, savings, and related provisions relating to enactment of Therapeutic Products Act 2018

1 Outline of transitional regime

- (1) The general scheme and effect of the transitional provisions in this Part are as follows:

Subpart 1—product approvals

- (a) pending applications for consents will generally continue to be dealt with under the 1981 Act by the Regulator, but subject to new rules (for example, about lapsed applications, transitional fees, and committees):
- (b) existing consents, and consents granted by the Regulator after commencement under this Part, will generally become approvals under this Act, but subject to new rules (for example, about cancellation, additional conditions after 2 years, and sponsor obligations):
- (c) temporary approvals will be created on commencement for products that were medicines before commencement but are devices after commencement, to allow time for new applications to be made under this Act:

Subpart 2—licences and other authorisations

- (d) pending applications for licences will generally be dealt with under this Act:
- (e) existing licences and other authorisations will generally carry forward into the new regime under this Act, but subject to new rules:
- (f) temporary licences and authorisations (generally for between 6 months and 2 years) will be created for certain matters, to allow time for new applications to be made under this Act:

Subpart 3—miscellaneous

- (g) existing proceedings will generally continue to be dealt with under the 1981 Act:
 - (h) other transitional provisions are included to ensure continuity.
- (2) This clause is by way of explanation only. If another provision of this Act conflicts with this clause, the other provision prevails.

2 Interpretation for this Part

- (1) In this Part, unless the context otherwise requires,—
- 1981 Act** means the Medicines Act 1981 and includes any regulations and other instruments made under that Act
- commencement** means the date on which this clause comes into force

consent means any of the following in respect of a therapeutic product:

- (a) a consent under section 20 of the 1981 Act (including a consent deemed to have been given under section 20(7) of that Act):
- (b) a provisional consent under section 23 of the 1981 Act:
- (c) a consent under section 24(3) of the 1981 Act:
- (d) a consent under this Part

existing authorisation means an authorisation (other than a consent or licence) or exemption under the 1981 Act that is in effect immediately before commencement and that authorises any activity that is a supply chain activity under this Act

existing consent means a consent that is in effect immediately before commencement

existing licence means a licence under Part 3 of the 1981 Act that is in effect immediately before commencement

pending application means an application that was made before commencement under the 1981 Act but that was not determined before commencement.

- (2) Any term that is used in this Part, but not defined in this Act, has the same meaning as in the 1981 Act.

Subpart 1—Product approvals

Pending applications for consent for medicines

3 Treatment of pending applications

- (1) This clause applies to any pending application for consent that was made under section 21 or 23 of the 1981 Act.
- (2) The Regulator may consider and determine the application, and give consent or not, as if the 1981 Act, and not this Act, were in force and as if the Regulator were the Minister.
- (3) However, this clause is subject to the rest of this Part.

4 Power to lapse pending applications

- (1) This clause applies to any pending application referred to in **clause 3**—
 - (a) if the Regulator considers, on an initial evaluation of the application, that the application is substantially deficient; or
 - (b) if, before commencement, the Director-General issued a requirement under section 21(4) or (5) of the 1981 Act (for example, to supply samples or further information), and the person in whose name the application was made does not comply with the requirement within 6 months after the requirement was issued; or

- (c) if, after commencement, the Director-General issues a requirement under section 21(4) or (5) of the 1981 Act and advises the person in whose name the application was made of the consequences of failing to comply with the requirement, but the person does not comply with the requirement within 6 months after the requirement is issued.
- (2) The Regulator may treat the application as lapsed and must inform the person in whose name the application was made accordingly.
- (3) The Regulator need not refund any fee paid under the 1981 Act or this Act if the application lapses under this clause.

5 Pending applications if matter before appropriate committee

- (1) This clause applies to any pending application referred to in **clause 3** if,—
 - (a) before commencement, the Minister referred the application to the appropriate committee under section 22(2) of the 1981 Act; but
 - (b) that committee had not reported, before commencement, on the matter with a recommendation as to the decision that the Minister should make.
- (2) The matter must be dealt with as follows:
 - (a) the Regulator may refer the matter to any appropriate committee appointed by the Regulator to assist the Regulator under this Act and that committee may consider the matter and report on the matter to the Regulator with a recommendation as to the decision under the 1981 Act that the Regulator should make; and
 - (b) the Regulator must otherwise consider and determine the application, and give consent or not, as if the 1981 Act, and not this Act, were in force.

6 Pending applications if matter before Medicines Review Committee

- (1) This clause applies to any pending application referred to in **clause 3** if—
 - (a) the Minister referred an objection, before commencement, to the Medicines Review Committee under section 22(5) of the 1981 Act; but
 - (b) the committee had not reported, before commencement, on the matter with a recommendation as to the decision that the Minister should make.
- (2) The matter must be dealt with as follows:
 - (a) the Regulator must refer the matter to a review panel convened under **section 201** of this Act; and
 - (b) the panel must review the matter and make a recommendation to the Regulator as to the decision under the 1981 Act that the Regulator should make; and
 - (c) the Regulator must otherwise consider and determine the application, and give consent or not, as if the 1981 Act, and not this Act, were in force.

7 Transitional evaluation fee for pending applications for consent

- (1) This clause applies to any pending application referred to in **clause 3** if—
 - (a) the application was made after the date on which this Act receives Royal assent but before commencement; and
 - (b) evaluation work did not start before commencement.
- (2) In this clause, **evaluation work** means either or both of the following in respect of the application:
 - (a) the Minister considering and weighing the matters referred to in section 22(1) of the 1981 Act;
 - (b) the appropriate committee considering the matter under section 22(2) of the 1981 Act.
- (3) The person in whose name the application was made must pay the prescribed transitional evaluation fee specified in the regulations.

8 Pending applications if product contains new organism

- (1) This clause applies to any pending application referred to in **clause 3** in respect of a qualifying new medicine within the meaning of the 1981 Act if, before commencement, a notice was deposited with the Director-General that is a sufficient application for the consent of the Minister under section 20 of the 1981 Act.
- (2) If a consent is given under **clause 3, 5, or 6** in respect of the application, the Regulator may grant an approval under section 38I of the Hazardous Substances and New Organisms Act 1996 for the release of a qualifying new medicine if they are acting under a delegation from the EPA given under section 19 of that Act.
- (3) If the Regulator declines to give consent under this Part because the new organism is not a qualifying new medicine, section 24B of the 1981 Act continues to apply as if the 1981 Act, and not this Act, were in force.

9 Pending applications in respect of special emergency

- (1) This clause applies to any therapeutic product in respect of which—
 - (a) an application was made, before commencement, under section 24D of the 1981 Act for the Minister's approval to distribute, sell, or advertise, in a special emergency, a medicine that is or contains a hazardous substance or new organism; and
 - (b) the Minister did not make a decision, before commencement, whether to give approval under that section.
- (2) The Regulator may consider and determine the application under **Part 5** of this Act as if it were an application for a permit.

*Consents for medicines under 1981 Act***10 Consents become approvals**

- (1) Every existing consent becomes an approval under **Part 4** of this Act on commencement.
- (2) Every consent given by the Regulator under **clause 3, 5, or 6** becomes an approval under **Part 4** of this Act immediately after it is given.
- (3) Every approval created by this clause—
 - (a) has the same expiry date (if any) as the consent had under the 1981 Act; and
 - (b) is an approval of a medicine as described in that consent and for the purpose described in that consent.
- (4) **Subclauses (1) and (2)** do not apply to a product that is an approval-exempt product.
- (5) However, this clause is subject to the rest of this Part.

11 Medicines grandfathered under Food and Drugs Act 1947

- (1) This clause applies to a medicine that did not require consent under the 1981 Act because a notice had been deposited with the Director-General under section 11B or 11C of the Food and Drugs Act 1947.
- (2) **Subclause (3)** applies if—
 - (a) a notice was deposited for the medicine under section 24(1) of the 1981 Act at any time within the 2-year period before commencement; and
 - (b) a further period of at least 90 days after the date on which the notice is deposited with the Director-General has expired; and
 - (c) the Director-General has not given notice to the importer or manufacturer under section 24(4) or (5) of the 1981 Act.
- (3) An approval is created for the medicine as if **clause 10** applied.
- (4) If **subclause (3)** does not apply, a temporary approval is created as follows:
 - (a) the medicine is deemed to be an approved product under the temporary approval to the extent that the import, export, or supply (as applicable) of the medicine was lawful before commencement; and
 - (b) the temporary approval has an expiry date that is—
 - (i) the first anniversary of commencement, if the sponsor notifies the Regulator, within 3 months after commencement, of the name, dose form, active ingredients, strength, and responsible manufacturer of the medicine; and
 - (ii) the day that is 3 months after commencement, in any other case.

12 Existing changed medicine notices

- (1) This clause applies to any notice deposited under section 24(1) of the 1981 Act before commencement and in respect of which the 90-day period referred to in section 24(3) of the 1981 Act has not expired before commencement.
- (2) The 1981 Act continues to apply to the matter until the end of the 90-day period as if the 1981 Act, and not this Act, were in force and as if the Regulator were the Director-General.
- (3) If the Regulator forms an opinion referred to in section 24(5) of the 1981 Act within that 90-day period, then, on the expiry of the 90-day period,—
 - (a) that Act ceases to apply to the matter; and
 - (b) the person who deposited the notice must apply to the Regulator for an approval under **Part 4** of this Act in respect of the medicine.
- (4) Until an application for approval under **subclause (3)(b)** is determined, the approval created by **clause 10** continues in respect of the unchanged medicine.

13 Approvals in respect of special emergencies become permits

- (1) Every approval granted under section 24D of the 1981 Act before commencement (an **existing special emergency approval**) becomes a permit under **Part 5** of this Act on commencement.
- (2) Every permit created by this clause—
 - (a) has the same expiry date as the existing special emergency approval had under the 1981 Act; and
 - (b) is subject to the same conditions as the existing special emergency approval was subject to under the 1981 Act; and
 - (c) is subject to the additional conditions (if any) related to the matters referred to in **clause 16** that are specified in the rules as applicable to permits created by this Part for existing special emergency approvals.
- (3) If an existing special emergency approval becomes a permit under this clause, the person who made the application under section 24D of the 1981 Act becomes the permit holder under this Act, with the same obligations as a permit holder of a permit under **Part 5** of this Act (including to pay fees).
- (4) Every permit created by this clause may be dealt with as if it had been granted under **Part 5** of this Act, including, for example, as follows:
 - (a) the permit may be cancelled under this Act as if it were a permit granted under **Part 5**; and
 - (b) the Regulator has the same powers and duties as the Regulator has in respect of permits granted under **Part 5**.

*New temporary approvals created***14 Temporary approval for products that were medicines before commencement but are devices after commencement**

- (1) This clause applies to a product that,—
 - (a) before commencement, was a medicine to which an existing consent applied; and
 - (b) after commencement, is within the definition of a medical device, but not of a medicine, in this Act.
- (2) On commencement, a temporary approval is created as follows:
 - (a) the product is deemed to be an approved product that is a medical device under the temporary approval; and
 - (b) the temporary approval has an expiry date that is the day that is 6 months after commencement.
- (3) **Subclause (4)** applies to the product if a valid application for product approval under **Part 4** of this Act is made to the Regulator before the day that is 1 year after commencement.
- (4) On the date of application, a temporary approval is created as follows:
 - (a) the product is deemed to be an approved product that is a medical device under the temporary approval; and
 - (b) the temporary approval has an expiry date that is the day that is the date that the Regulator determines that application.
- (5) However, this clause is subject to the rest of this Part.

*General provisions that apply to all approvals created by this Part***15 Approvals created by this Part may be dealt with under this Act**

Every approval created by this Part may be dealt with as if it had been granted under **Part 4** of this Act, including, for example, as follows:

- (a) the approval may be varied or cancelled under this Act as if it were an approval granted under **Part 4**; and
- (b) the Regulator has the same powers and duties in respect of the product to which the approval relates as the Regulator has in respect of products approved under **Part 4**.

16 Additional conditions apply to approvals created by this Part

- (1) Every approval created by this Part is subject, on and after the relevant date, to the conditions related to the following matters that are specified in the rules as applicable to approvals created by this Part:
 - (a) labelling:

- (b) information about the product.
- (2) The relevant date is the later of—
 - (a) the date that is the second anniversary of commencement; and
 - (b) the date on which the Regulator gives consent under this Part.
- 17 Sponsors for approvals created by this Part**
- (1) If a consent becomes an approval under **clause 10**, the person in whose name the application for consent was made—
 - (a) becomes the sponsor of the product to which the approval relates; and
 - (b) is subject to the same conditions that applied to the person under the existing consent; and
 - (c) has the same obligations as a sponsor who had applied for the approval under **Part 4** of this Act (including to pay fees and to comply with the conditions on the approval).
- (2) If an approval is otherwise created by this Part, the sponsor of the product—
 - (a) is subject to the same conditions that applied to that person under any authorisation that the approval replaces; and
 - (b) is subject to any conditions that were otherwise imposed on that person by the Minister under the 1981 Act in relation to the product or any activity related to the product; and
 - (c) has the same obligations as a sponsor of an approval granted under **Part 4** of this Act (including to pay fees and to comply with the conditions on the approval).
- (3) Every approval created by this Part is subject, on and after commencement, to a condition that, if the person who becomes the sponsor is not the responsible manufacturer of the product, the person must give the Regulator a statutory declaration that the person has a contractual relationship with the responsible manufacturer that meets the criteria specified in the rules on that matter for being a sponsor.
- (4) **Subclause (5)** applies if—
 - (a) there is no sponsor to whom this clause applies (for example, because the person in whose name the application for consent was made has died or, if a body corporate, has been wound up); or
 - (b) there is otherwise no sponsor who meets the criteria for being the sponsor of an approved product under **section 97**.
- (5) The Regulator may notify a person who meets the criteria for being the sponsor of an approved product under **section 97** that the approval created by this Part is subject to the person becoming the sponsor under this Act, and this clause then applies to that person accordingly.

*Other matters***18 Existing notices under section 36(1) of 1981 Act**

- (1) This section applies if, before commencement, the Director-General—
 - (a) issued a notice in respect of a medicine under section 36(1) of the 1981 Act (which applies if the Director-General has reason to believe a medicine may be unsafe or ineffective); but
 - (b) has not issued a notice under section 36(3) of that Act.
- (2) The Regulator must, after commencement, consider and determine the matter under this Act.
- (3) **Subclause (4)** applies if—
 - (a) the Regulator is not satisfied about the safety and efficacy of the product; or
 - (b) before commencement, the matter was referred under section 36(2) of the 1981 Act to a committee established under that Act; or
 - (c) the Regulator otherwise thinks it necessary or desirable.
- (4) The Regulator may refer the matter to any appropriate committee appointed by the Regulator to assist the Regulator under this Act, and that committee may consider the matter and report on the matter to the Regulator with a recommendation as to the decision under this Act that the Regulator should make.

19 Existing notices under section 36(3) or 37 of 1981 Act

- (1) **Subclause (2)** applies if, before commencement, the Minister prohibits certain matters in respect of a medicine by issuing a notice under section 36(3)(a) or 37 of the 1981 Act.
- (2) No temporary approval is created under this Part in respect of the product.
- (3) The sponsor of the product must apply for approval of the product under **Part 4** of this Act.
- (4) **Subclause (5)** applies if, before commencement, the Minister imposes any condition in respect of a medicine by issuing a notice under section 36(3)(b) of the 1981 Act.
- (5) A temporary approval is created under this Part in respect of the product that is subject to those conditions.

20 Existing notices under section 38 of 1981 Act

- (1) This section applies if, before commencement, the Minister issued a notice under section 38 of the 1981 Act (which relates to unsafe medical devices) in respect of a therapeutic product.
- (2) No temporary approval is created under this Part in respect of the product.

- (3) The sponsor of the product must apply for approval of the product under **Part 4** of this Act.

21 Related products under Part 7 of 1981 Act

- (1) This clause applies to any related product within the meaning of Part 7 of the 1981 Act.
- (2) Any pending application under sections 20 to 22 of the 1981 Act (as applied by section 96(1) of the 1981 Act) must be considered and determined by the Regulator under this Part as if it were an application for approval of a medicine.
- (3) Any notice lodged before commencement under section 24 of the 1981 Act (as applied by section 96(2) of the 1981 Act) must be considered and determined by the Regulator under **clause 12** as if the product were a medicine.
- (4) However, **subclause (3)** does not apply if the Regulator determines that the product is not within the definition of a medicine in this Act or if the regulations specify that it is not a medicine.
- (5) This Part applies to any existing consent granted in respect of a related product as if the existing consent were for a medicine.

Protection of confidential information

22 Continuation of protections for confidential supporting information

Sections 23B and 23C of the 1981 Act continue to apply to all confidential supporting information (as defined in section 23A of the 1981 Act) that was contained in an application for an innovative medicine received before commencement.

23 Meaning of innovative medicine application

- (1) This section applies for the purpose of determining whether an application for approval of a medicine (**medicine A**) made by a person (**person A**) is an innovative medicine application under **section 120**.
- (2) In the definition of **innovative medicine application, paragraph (b)**, the reference to an application for approval of a medicine—
 - (a) includes either of the following:
 - (i) an application for the consent of the Minister under section 20 of the Medicines Act 1981 in relation to a medicine;
 - (ii) an application for the provisional consent of the Minister under section 23 of the Medicines Act 1981 in relation to a medicine; but
 - (b) does not include an application, made by person A, for provisional consent in relation to medicine A.

Subpart 2—Licences and other authorisations

Pending applications for licences and other authorisations

24 Treatment of pending applications for licences

- (1) This clause applies to any pending application for a licence under Part 3 of the 1981 Act.
- (2) The Regulator may consider and determine an application specified in column 1 of the following table as if it were an application that had been made under this Act as specified in column 2 of the table:

Pending applications under 1981 Act	How considered and determined under this Act
Application for a licence to manufacture medicines	As an application for a licence to manufacture medicines
Application for a licence to hawk medicines	Lapses— <i>see</i> clause 25
Application for a licence to sell prescription medicines, restricted medicines, or pharmacy-only medicines by wholesale	As an application for a licence for wholesale supply of category 1, 2, or 3 medicines
Application for a licence to sell pharmacy-only medicines by retail	As an application for a licence for non-wholesale supply of category 3 medicines
Application for a licence to pack or label medicines	As an application for a licence to manufacture medicines
Application for a licence to operate a pharmacy	As an application for a licence to carry on a pharmacy business

- (3) However, this clause is subject to the rest of this Part.

25 Pending applications to hawk medicines lapse

- (1) This clause applies to any pending application for a licence under Part 3 of the 1981 Act to hawk medicines.
- (2) The application lapses on commencement.
- (3) The Regulator must—
 - (a) inform the person in whose name the application was made what needs to be done to deal with the matter under this Act; and
 - (b) refund any fee paid under the 1981 Act.

26 Pending applications for approvals to conduct clinical trial

- (1) This clause applies to every pending application for an approval to conduct a clinical trial.
- (2) The Regulator may consider and determine the application as if it were an application that had been made under this Act for a licence to conduct a clinical trial.

*Existing licences under 1981 Act***27 Treatment of existing licences**

- (1) An existing licence under the 1981 Act that is specified in column 1 of the following table becomes, on commencement, a licence under this Act as specified in column 2 of the table:

Existing licences under 1981 Act	What they become under this Act
Licence to manufacture medicines	Licence to manufacture medicines that covers the same medicines as the existing licence
Licence to hawk medicines	Licence for wholesale supply of category 1, 2, or 3 medicines that covers the same medicines as the existing licence
Licence to sell prescription medicines, restricted medicines, or pharmacy-only medicines by wholesale	Licence for wholesale supply of category 1, 2, or 3 medicines that covers the same medicines as the existing licence
Licence to sell pharmacy-only medicines by retail	Licence for non-wholesale supply of category 3 medicines that covers the same medicines as the existing licence
Licence to pack or label medicines	Licence to manufacture medicines that covers the same medicines as the existing licence
Licence to operate a pharmacy	Licence to carry on a pharmacy business

- (2) A licence created under **subclause (1)** has the same expiry date as the existing licence it replaces.
- (3) However, this clause is subject to the rest of this Part.

*Existing authorisations under 1981 Act***28 Three-month temporary authorisation for authorised prescribers**

- (1) A person authorised under section 25 of the 1981 Act to do any of the things set out in subsection (1)(a), (d), or (e) of that section continues (despite this Act) to be authorised to do those things, as if the 1981 Act, and not this Act, were in force.
- (2) The authorisation continued by **subclause (1)** ceases 3 months after commencement

29 Continuation of prescriptions

A person may treat a prescription given under the 1981 Act before commencement by an authorised prescriber, veterinarian, or delegated prescriber as if it were a complying prescription for the purpose of this Act unless and until an expiry event specified in the regulations occurs in relation to it.

30 Three-month temporary authorisation for medical practitioners

- (1) A person who is authorised under section 29 of the 1981 Act to supply a new medicine for the treatment of a particular patient of the medical practitioner

may continue (despite this Act) to so supply that medicine as if the 1981 Act, and not this Act, were in force.

- (2) The authorisation continued by **subclause (1)** ceases 3 months after commencement.

31 Twelve-month temporary authorisation for existing standing orders

- (1) Every standing order issued under the 1981 Act that is in force immediately before commencement becomes a complying standing order under this Act on commencement.
- (2) The authorisation continued by **subclause (1)** ceases on the earliest of—
- (a) the day that is 12 months after commencement; and
 - (b) the expiry date (if any) specified in the standing order issued under the 1981 Act; and
 - (c) the date on which the standing order issued under the 1981 Act is revoked.
- (3) Until the authorisation ceases,—
- (a) any regulations made under section 105(1)(qb) of the 1981 Act continue to apply; and
 - (b) the issuer may revoke the standing order as if it were issued under this Act; and
 - (c) the 1981 Act otherwise continues to apply.

32 Existing biotechnical procedures (xenotransplantation) under Part 7A of 1981 Act

- (1) **Subclause (2)** applies to any pending application that was made under Part 7A of the 1981 Act.
- (2) After commencement, either—
- (a) the Regulator may consider and determine the application as if it were an application for a licence under **Part 5** of this Act (unless the applicant withdraws the application); or
 - (b) the applicant may make a new application for approval under **Part 4** of this Act.
- (3) **Subclause (4)** applies to any authorisation that was granted before commencement by a notice under section 96C of the 1981 Act or by an Order in Council under section 96D of the 1981 Act.
- (4) On commencement, the authorisation becomes a licence under **Part 5** of this Act that authorises the same person or body of persons to conduct the particular specified biotechnical procedure that was authorised under the 1981 Act.

*Temporary licences***33 Temporary licences for medical devices**

- (1) This clause applies to a medical device in respect of which, before commencement, 1 or more of the following activities (**pre-commencement activity**) was lawfully being carried on:
 - (a) import;
 - (b) manufacture;
 - (c) supply.
- (2) On commencement, a temporary licence is created that—
 - (a) authorises the pre-commencement activity to be carried on, and other things to be done with the device, to the extent that was lawful before commencement; and
 - (b) has an expiry date that is the day that is 6 months after commencement.
- (3) If a valid application for product approval under Part 4 of this Act is made to the Regulator before the day that is 6 months after commencement, a temporary licence is created on the date of application that—
 - (a) authorises the applicant to carry on the pre-commencement activity, and to do anything else with the device, to the extent that was lawful before commencement; and
 - (b) has an expiry date that is the date that the Regulator determines that application.
- (4) If a valid application for a licence under **Part 5** of this Act is made to the Regulator before the day that is 6 months after commencement, a temporary licence is created on the date of application that—
 - (a) authorises the applicant to carry on the controlled activities specified in the application to the extent that was lawful before commencement; and
 - (b) has an expiry date that is the date on which the Regulator determines that application.

34 Temporary licences for supply of products that become therapeutic products on commencement

- (1) This clause applies to a product that,—
 - (a) before commencement, is not within the definition of a medicine or a medical device in the 1981 Act; and
 - (b) after commencement, is within the definition of a therapeutic product under this Act (eg a cell or tissue product); and
 - (c) at commencement, is lawfully being supplied in New Zealand.
- (2) On commencement, a temporary licence is created that—

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- (a) authorises the supply of the product, and other things to be done with the product, to the extent that was lawful before commencement; and
 - (b) has an expiry date that is the day that is 1 year after commencement.
- (3) If a valid application for product approval under **Part 4** of this Act is made to the Regulator before the day that is 1 year after commencement, a temporary licence is created on the date of application that—
- (a) authorises the applicant to supply the product, and to do anything else with the product, to the extent that was lawful before commencement; and
 - (b) has an expiry date that is the date on which the Regulator determines that application.
- (4) If a valid application for a licence under **Part 5** of this Act is made to the Regulator before the day that is 1 year after commencement, a temporary licence is created on the date of application that—
- (a) authorises the applicant to carry on the controlled activities specified in the application to the extent that was lawful before commencement; and
 - (b) has an expiry date that is the date on which the Regulator determines that application.

35 Twelve-month temporary licence for existing approved clinical trials

- (1) This clause applies to a clinical trial that is lawfully being carried out at commencement if, on commencement, the clinical trial, and the persons (the **investigators**) who conduct the trial, have been approved by the Director-General on the recommendation of the Health Research Council of New Zealand under section 30 of the 1981 Act.
- (2) The person who made the application under section 30(2) of the 1981 Act must apply, no later than 12 months after commencement, for a licence under **Part 5** of this Act to carry on the activity.
- (3) A temporary licence is created as follows:
- (a) the licence authorises the investigators to conduct the trial, and carry out related supply chain activities, to the extent that was lawfully being done in New Zealand before commencement; and
 - (b) the licence has an expiry date that is,—
 - (i) if a valid application for a licence is made as required by **sub-clause (2)** and if the trial meets the requirements set under this Act in respect of clinical trials, the date on which the Regulator determines the application; and
 - (ii) in any other case, 12 months after commencement.

36 Six-month temporary licence for existing unapproved clinical trials

- (1) This clause applies to a clinical trial that is lawfully being carried out at commencement if, on commencement, the clinical trial and the persons (the **investigators**) who conduct the trial have not been approved by the Director-General on the recommendation of the Health Research Council of New Zealand under section 30 of the 1981 Act.
- (2) The person identified in the clinical trial protocol as the principal investigator must apply, no later than 6 months after commencement, for a licence under **Part 5** of this Act to carry on the activity.
- (3) A temporary licence is created as follows:
 - (a) the licence authorises the investigators to conduct the trial, and carry out related supply chain activities, to the extent that was lawfully being done in New Zealand before commencement; and
 - (b) the licence has an expiry date that is,—
 - (i) if a valid application for a licence is made as required by **sub-clause (2)** and if the trial meets the requirements set under this Act in respect of clinical trials, the date on which the Regulator determines the application; and
 - (ii) in any other case, 6 months after commencement.

*General provisions that apply for this subpart***37 Licences created under this subpart**

- (1) Every licence that is created under **clause 27** to replace an existing licence, and every licence that is created under **clause 32(4)** to replace an existing authorisation,—
 - (a) is on the same terms as any existing licence or authorisation that it replaces; and
 - (b) is also subject, on and after the relevant date specified in the rules, to the additional conditions that are specified in the rules as applicable to licences created under this Part.
- (2) Every other licence that is created under this subpart in respect of an activity that was lawful under the 1981 Act authorises the activity on the same terms as were lawful under the 1981 Act.
- (3) Every licence that is created under this subpart may be dealt with as if it had been granted under **Part 5** of this Act, including, for example, as follows:
 - (a) the licence may be varied or cancelled under this Act as if it were a licence granted under **Part 5**; and
 - (b) the Regulator has the same powers and duties in respect of the licence as the Regulator has in respect of licences granted under **Part 5**.

- (4) The person who was the licensee under an existing licence, or who was authorised under any other authorisation under the 1981 Act, becomes the licensee under the licence created under this Part, with the same obligations as a licensee of a licence granted under **Part 5** (including to pay fees).
- (5) However, this clause is subject to the rest of this Part.

Subpart 3—Miscellaneous transitional provisions

38 New powers available under this Part

- (1) **Subparts 2 to 5 of Part 6** of this Act (which relate to investigative powers, administrative matters, etc) apply after commencement—
 - (a) when any pending application, proceeding, or other matter is considered or determined under this Part; and
 - (b) for the purpose of commencing or continuing any enforcement action in respect of a breach of the 1981 Act.
- (2) **Subclause (1)** applies whether the 1981 Act or this Act applies to the matter after commencement under this Part.

39 Fees for matters dealt with under this Act

- (1) This clause applies—
 - (a) if any pending application or proceeding is to be considered or determined under this Act by reason of this Part; or
 - (b) if any approval, licence, permit, or other authorisation is created under this Part to replace an existing consent, licence, or other authorisation.
- (2) The Regulator may require that all or part of the relevant fee that is payable in respect of the same matter under this Act be paid by the relevant person who would be liable to pay the fee if the application, proceeding, or other matter had started under this Act.
- (3) The Regulator is not required to process the application, proceeding, or other matter until that fee has been paid.
- (4) However, the Regulator must not require any fee in respect of the creation under this Part of a licence to conduct a clinical trial that was approved by the Director-General on the recommendation of the Health Research Council of New Zealand under section 30 of the 1981 Act.
- (5) This clause does not limit **clause 7** (transitional evaluation fee for pending applications for consent).

40 Proceedings related to offences commenced under 1981 Act

Any proceedings related to offences that, on commencement, have commenced but have not been completed under the 1981 Act must be continued and completed in all respects as if the 1981 Act had not been repealed.

41 Pending appeals to Medicines Review Committee if licensing authority refused to grant licence

- (1) This clause applies to any appeal that was lodged before commencement under section 88 of the 1981 Act but that was not determined before commencement.
- (2) The matter must be dealt with as follows:
 - (a) the Regulator must refer the matter to a review panel convened under **section 201** of this Act; and
 - (b) the panel must review the matter and notify the Regulator of its decision under **Part 6** of this Act, with a recommendation as to the decision under the 1981 Act that the Regulator should make; and
 - (c) the Regulator must otherwise consider and determine the application, and give consent or not, as if the 1981 Act, and not this Act, were in force.

42 Regulations may extend transitional periods

Regulations may extend any transitional period specified in this Part.

43 Purpose of Act includes orderly transition to this Act

- (1) This clause applies to the criteria in this Act (for example, for granting a permit) that refers to whether it is necessary or desirable in order to promote the purpose of this Act.
- (2) The criteria must be read as if the purpose of this Act includes an orderly transition to this Act.

Schedule 2

Reviewable decisions

s 200

Section	Reviewable decision	Who may apply for review
<i>Approvals</i>		
1	s 94 Refusal to approve product	Applicant
2	s 94 Terms of approval when granted (including conditions)	Sponsor
4	s 107 Refusal to vary approval on application	Sponsor
5	s 107 Variation of approval (including conditions)	Sponsor
6	s 109 Cancellation of approval	Sponsor
<i>Licences and permits</i>		
7	ss 127, 134 Refusal to grant licence or permit	Applicant
8	ss 127, 134 Terms of licence or permit when granted	Licensee or permit holder
9	s 139 Conditions imposed on licence or permit when granted	Licensee or permit holder
10	s 140 Refusal to vary licence or permit on application	Licensee or permit holder
11	s 140 Variation of licence or permit (including conditions)	Licensee or permit holder
12	s 143 Suspension or cancellation of licence or permit	Licensee or permit holder
13	s 147 Refusal to lift suspension on application	Licensee or permit holder
<i>Regulatory powers</i>		
14	ss 181, 182 Refusal to vary or revoke regulatory order	Applicant

Schedule 3

Regulations, rules, and Regulator's notices

ss 261, 262, 263

1 Matters that may be specified in regulations

Interpretation

- (1) Products that are or are not therapeutic products (*see* **section 16**)
- (2) Categorisation criteria for each category of medicines (*see* **section 19**)
- (3) Medical devices that are supply-restricted devices or use-restricted devices and the restrictions applying to them (*see* **section 22**)
- (4) Therapeutic products that are prohibited products (*see* **section 25**)
- (5) Businesses that are not pharmacy businesses and circumstances in which wholesale supply is a pharmacy activity (*see* **section 36**)
- (6) Requirements and expiry events for complying prescriptions (*see* **section 38**)
- (7) Requirements and expiry events for complying special clinical needs supply authorities (*see* **section 39**)
- (8) Requirements and revocation events for, and effect of, complying standing orders (*see* **sections 40 and 41**)

Controlled activities and supply chain activities

- (9) Obligations of persons in supply chain (*see* **section 55**)

Authorisations

- (10) Permitting wholesale supply of medicines and medical devices by the following persons, and requirements in relation to that supply:
 - (a) pharmacists (*see* **section 59**):
 - (b) health practitioners (*see* **section 63**):
 - (c) veterinarians (*see* **section 68**)
- (11) Permitting special clinical needs supply authorities to be issued and specifying other criteria for their issue (*see* **sections 64 and 69**)
- (12) Criteria for manufacturers, and manufacturing requirements, for custom-made medical devices (*see* **section 75**)
- (13) Products that cannot be imported under personal use authorisation (*see* **sections 76 and 77**)
- (14) Authorising a person to do anything that would otherwise contravene any of **sections 51 to 55** (*see* **section 79**)

Other offences

- (15) Criteria for granting a permit relating to a prohibited product (*see* **section 81(2)**)

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- (16) Communications that are not advertisements (*see* **section 82**)
- (17) Advertisement and distribution requirements (*see* **section 83**)
- Approvals*
- (18) How products are to be described in approvals (*see* **section 98(b)**)
- (19) Period for which an approval remains in force (*see* **section 103(2)(b)**)
- (20) Procedures for cancelling an approval (*see* **section 110**)
- (21) Information to be included in product register (*see* **section 113**)
- (22) Obligations of sponsors (*see* **section 118**)
- (23) Circumstances in which protected active ingredient information may be disclosed (*see* **section 122**)
- Licences and permits*
- (24) Information to be included in a licence or permit (*see* **sections 124 and 132**)
- (25) Procedural requirements for suspending or cancelling a licence or permit (*see* **section 144**)
- (26) Information to be included in licences and permits register (*see* **section 152**)
- (27) Obligations of responsible persons (*see* **section 158**)
- Regulator*
- (28) Safety monitoring obligations (*see* **section 160**)
- (29) How applications for review are to be made and any procedural requirements (*see* **section 200**)
- (30) How review panels are to be convened (*see* **section 201**)
- (31) Procedures for review panels (*see* **section 202**)
- (32) Recognition criteria for recognised authorities (*see* **section 207**)
- Enforcement*
- (33) Compliance standards for specified standard defence (*see* **section 246**)
- (34) Infringement circumstances and infringement fees for infringement offences (*see* **section 250**)
- (35) Forms for, and information to be included in, infringement notices or reminder notices (*see* **section 254**)
- Administrative matters*
- (36) Fees and charges (*see* **section 257**)
- Transitional matters*
- (37) Extension of transitional periods specified in **Part 1 of Schedule 1**.

2 Matters that may be specified in rules*Interpretation*

- (1) Maximum compoundable quantities of medicines (*see section 28*)
- (2) Qualification, training, and competency requirements for qualified pharmacy workers (*see section 37*)
- (3) Levels of supervision for qualified pharmacy workers (*see sections 37 and 60*)

Product approval

- (4) Criteria for approval of products (*see section 95(1)(c)*)
- (5) Product standards (*see section 96*)
- (6) Criteria for sponsor's relationship with the responsible manufacturer (*see section 97(c)*)
- (7) Changes that constitute a major change (*see section 100(1)(b)*)
- (8) Minor changes that are notifiable (*see section 101*)
- (9) Conditions to which approvals are subject (*see section 105*)
- (10) Grounds to cancel an approval (*see section 108(k)*)

Licences and permits

- (11) Number of responsible persons required for a licence (*see section 128(1)(b)*)
- (12) Criteria for granting licences (*see section 128(1)(h)*)
- (13) Qualification, training, and competency requirements for responsible persons (*see section 130*)
- (14) Criteria for granting permits (*see section 135(f)*)
- (15) Conditions to which licences or permits are subject (*see section 138*)
- (16) Grounds to suspend or cancel a licence or permit (*see section 141 or 142*)

Administrative matters

- (17) How notice is to be given to the Regulator and any procedural requirements (*see section 218*)
- (18) Procedural requirements for applications (*see section 211(2)*)
- (19) Forms (other than those required to be specified in the regulations).

3 Matters that may be specified in Regulator's notices

- (1) Designating persons or bodies as ethics approval entities (*see the definition of ethics approval entity in section 14*)
- (2) Therapeutic products that are medicines, AMIs, medical devices, or type-4 products (*see sections 18, 20, 21, and 23*)
- (3) Therapeutic products that are approval-exempt products (*see section 114*)
- (4) Designating persons or bodies as recognised authorities (*see section 207*).

Schedule 4
Amendments to other enactments

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Part 1
Amendments to Acts

Accident Compensation Act 2001

Agricultural Compounds and Veterinary Medicines Act 1997

Animal Products Act 1999

Animal Welfare Act 1999

Biosecurity Act 1993

Contraception, Sterilisation, and Abortion Act 1977

Copyright Act 1994

Coroners Act 2006

Corrections Act 2004

Customs and Excise Act 2018

Fair Trading Act 1986

Food Act 2014

Hazardous Substances and New Organisms Act 1996

Health Act 1956

Human Assisted Reproductive Technology Act 2004

Human Tissue Act 2008

Land Transport Act 1998

Maritime Transport Act 1994

Misuse of Drugs Act 1975

New Zealand Public Health and Disability Act 2000

Ombudsmen Act 1975

Patents Act 2013

Psychoactive Substances Act 2013

Public Safety (Public Protection Orders) Act 2014

Returning Offenders (Management and Information) Act 2015

Smoke-free Environments Act 1990

Substance Addiction (Compulsory Assessment and Treatment) Act 2017

Summary Proceedings Act 1957

Trade Marks Act 2002

Trans-Tasman Mutual Recognition Act 1997

Veterans' Support Act 2014

Part 2

Amendments to legislative instruments

Accident Insurance (Insurer Returns) Regulations 1999

Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011

Animal Products (Exemptions and Inclusions) Order 2000

Corrections Regulations 2005

Dietary Supplements Regulations 1985

Electricity (Safety) Regulations 2010

Gas Governance (Critical Contingency Management) Regulations 2008

Health and Safety at Work (Hazardous Substances) Regulations 2017

Health (Needles and Syringes) Regulations 1998

Health Practitioners Competence Assurance (Restricted Activities) Order 2005

Oranga Tamariki (Residential Care) Regulations 1996