Version
as at 30 June 2024

Therapeutic Products Act 2023

Public Act	2023 No 37
Date of assent	26 July 2023
Commencement	see section 2

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Note

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

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

This Act is administered by the Ministry of Health.

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The Parliament of New Zealand enacts as follows:

1 Title

This Act is the Therapeutic Products Act 2023.

2 Commencement

(1) This Act comes into force on a date appointed by the Governor-General by Order in Council.

(2) However, subpart 2 of Part 11 comes into force on the day after Royal assent.

(3) To the extent that it is not previously brought into force under subsection (1) or (2), this Act comes into force on 1 September 2026.

(4) An Order in Council made under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

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

This note is not part of the Act.

Part 1
Preliminary provisions

3 Purpose

The purpose of this Act is to protect, promote, and improve the health of all New Zealanders by providing for the—

(a) acceptable safety, quality, and efficacy of medicines and active pharmaceutical ingredients across their life cycle; and

(b) acceptable safety, quality, and performance of medical devices across their life cycle; and

(c) acceptable safety and quality of natural health products across their life cycle and the substantiation of health benefit claims made about those products.

4 Principles guiding exercise of powers under Act

The Regulator, the Minister, 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, and their regulation should be proportionate to those benefits and risks:

(b) regulation of therapeutic products should support—

(i) the timely availability of those products; and

(ii) open and well-functioning markets for those products; and

(iii) innovation, including opportunities for Māori and other population groups; and

(iv) choice of, and equity of access to, therapeutic products for Māori and other population groups:

(c) there should be co-operation with overseas regulators 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

(1) This Act binds the Crown.

(2) An instrument of the Crown that is a Crown organisation (whether or not a body corporate)—

(a) must be treated as if it were a separate legal personality for the purpose of complying with this Act; and

(b) may be a sponsor, licensee, or permit holder in its own right.

(3) An instrument of the Crown that is neither a Crown organisation nor a body corporate—

(a) does not have separate legal personality; and

(b) cannot be a sponsor, licensee, or permit holder in its own right.

(4) This section is subject to subpart 8 of Part 8 (enforcement against the Crown).

Outline of regulatory scheme

7 Outline of regulatory scheme

(1) This Act regulates therapeutic products in New Zealand.

(2) This section and sections 8 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 the following 2 broad components:

(a) market authorisation requirements, which regulate which therapeutic products may be imported into, supplied in, or exported from New Zealand:

(b) controlled activity and supply chain activity requirements, which regulate how those therapeutic products can be dealt with and by whom.

8 What products are covered by regulatory scheme

(1) Therapeutic products are products that are intended for use in, on, or in relation to humans for therapeutic purposes (*see* sections 15 and 16).

(2) They are divided into 4 types—medicines, medical devices, active pharmaceutical ingredients (known as APIs), and natural health products (known as NHPs) (*see* sections 20, 22, 24, 28, and 29).

(3) Each type of therapeutic product includes a broad range of products. For example,—

(a) medicines include pain relief available at supermarkets (such as paracetamol), vaccines, chemotherapy medicines, and patient-specific genetic treatments:

(b) medical devices include products ranging from tongue depressors and bandages to implantable devices (such as pacemakers), cell-phone-based diagnostic software, and robotic surgery machines:

(c) APIs are the active ingredients of medicines, so they are as varied as medicines:

(d) NHPs include products such as vitamin and mineral supplements, herbal remedies, animal extracts, probiotics, enzymes, and essential fatty acids.

9 Market authorisations

(1) Therapeutic products (other than APIs) are regulated by means of market authorisations.

(2) Generally, a medicine, a medical device, or an NHP cannot be imported, supplied, or exported unless it has a market authorisation (*see* section 68).

(3) The process for getting a market authorisation is set out in Part 4. In broad terms, an applicant must satisfy the Regulator,—

(a) in the case of a medicine, about its safety, quality, and efficacy:

(b) in the case of a medical device, about its safety, quality, and performance:

(c) in the case of an NHP, about its safety and quality and about the health benefit claims the sponsor proposes to make about it.

(4) The process for doing that, what evidence has to be given to the Regulator, and the extent and nature of the Regulator's evaluation vary depending on the type of product and the likely benefits of, and risks associated with, it.

(5) Once a product has a market authorisation, the person to whom it was issued (known as the sponsor) is responsible for ensuring that the product conforms to the authorisation and meets the applicable product standards. They also have ongoing obligations in relation to such things as post-market surveillance, record keeping, and reporting (*see* subpart 2 of Part 4).

(6) This Act allows some products to be imported, supplied, or exported without them having a market authorisation (for example, medicines that require compounding, custom-made devices, and low-concentration NHPs).

(7) Also, a person may be able to import, supply, or export a therapeutic product that does not have a market authorisation if they have a licence or permit, or a provision of subpart 3 of Part 3 allows them to do so.

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. Those controls apply in addition to the requirement for products to have a market authorisation.

(2) The controlled activities, which are listed in section 70, include the following:

(a) manufacturing:

(b) wholesale and non-wholesale supply:

(c) exporting:

(d) prescribing and dispensing medicines:

(e) administering medicines and using medical devices:

(f) conducting clinical trials:

(g) carrying on a pharmacy business.

(3) What the controls are varies depending on the type of product and the circumstances in which the activity is carried on. In broad terms, no one is allowed to carry on a controlled activity unless a licence, permit, or provision of subpart 3 of Part 3 allows them to do so (*see* section 70).

(4) Although therapeutic products are products intended for human use, this Act also controls veterinary activities that involve the use of human medicines or medical devices for animal patients.

11 When controlled activities are allowed

(1) Various categories of people are allowed to carry on controlled activities in certain circumstances (*see* subpart 3 of Part 3). They include pharmacists, health practitioners, veterinarians, product sponsors, people who manufacture custom-made devices (such as prostheses), and NHP practitioners. The regulations may also allow other classes of people to carry on controlled activities.

(2) Licences and permits may also allow people to carry on controlled activities. Each licence or permit will set out which controlled activities are allowed, with which products, and on what conditions. The licensee or permit holder must comply with the terms and conditions of the licence or permit.

(3) The requirements for getting a licence or permit are set out in Part 5.

(4) Anyone who is authorised to carry on a controlled activity must also comply with requirements set out in the rules or regulations. For example, rules made for the purposes of section 73 may relate to matters such as—

(a) when, where, and how the activity is carried on:

(b) product information and consumer information:

(c) packages, packing, labelling, and identification:

(d) storage, handling, security, transport, and disposal:

(e) post-market surveillance and response:

(f) record keeping, auditing, and giving information to the Regulator.

12 Obligations on other people

(1) This Act also regulates other people who carry on a business or undertaking in the supply chain for therapeutic products, even if they are not carrying on controlled activities (*see* section 58).

(2) The requirements for people who are in the supply chain but are not carrying on a controlled activity may relate to the matters referred to in section 11(4), but will generally be less onerous than those for people carrying on controlled activities. Again, those controls are in addition to the requirement for products to have a market authorisation.

(3) This Act also imposes restrictions on advertising therapeutic products and making health benefit claims about NHPs. It also prohibits conduct such as tampering, making misrepresentations, giving false or misleading information, and failing to comply with regulatory or investigative requirements (*see* Part 6).

13 Administration of regulatory scheme

(1) The regulatory scheme is administered by the Therapeutic Products Regulator (*see* Part 9).

(2) The Regulator is responsible for issuing market authorisations and granting licences and permits.

(3) The Regulator carries out surveillance of therapeutic products with a market authorisation (or that are otherwise lawfully in the supply chain) to collect and evaluate information about—

(a) the safety, quality, and efficacy of medicines; and

(b) the safety, quality, and performance of medical devices; and

(c) the safety and quality of NHPs.

(4) The Regulator also monitors sponsors, people carrying on controlled activities, and other people in the supply chain to ensure that they are complying with their obligations under this Act (*see* subpart 1 of Part 7).

(5) The Regulator can make various kinds of regulatory orders if there are problems that create unacceptable risks to personal health or public health. They include recall orders, advertising remediation orders, and product moratorium orders (*see* subpart 3 of Part 7).

(6) The Regulator is also responsible for enforcing compliance with this Act (*see* Part 8). If someone is not complying, the Regulator has a range of tools with which to respond. They include—

(a) prosecuting for criminal offences:

(b) obtaining civil penalty orders:

(c) issuing infringement notices:

(d) accepting enforceable undertakings:

(e) obtaining injunctions:

(f) cancelling market authorisations:

(g) suspending or cancelling licences and permits.

(7) Not all of the tools are available in every case. Which are available, and which the Regulator chooses to use, depends on which provisions of this Act a person has contravened and the circumstances in which that happened.

(8) Subpart 6 of Part 8, section 300, and the general criminal law impose restrictions on when prosecutions, civil penalty orders, infringement notices, and undertakings can be used so that a person cannot be punished twice for the same conduct.

Part 2
Interpretation

Subpart 1—General

14 Interpretation

In this Act, unless the context otherwise requires,—

act unprofessionally means,—

(a) in relation to a health practitioner, to behave in a way that would give the Health Practitioners Disciplinary Tribunal grounds under section 100 of the Health Practitioners Competence Assurance Act 2003 to make an order against them; and

(b) in relation to a veterinarian, to behave in a way that would give the Veterinary Council of New Zealand grounds under section 50 of the Veterinarians Act 2005 to take disciplinary action against them

active moiety is defined in section 151

additive or formulation aid is defined in section 30

administer, in relation to a medicine or an NHP, is defined in section 36

advertisement is defined in section 196

advertising remediation order is defined in section 221

alleged contravention, in relation to an enforceable undertaking, is defined in section 294

API (which is an acronym of active pharmaceutical ingredient) is defined in section 28

associate, in relation to a rongoā practitioner, is defined in section 31

authorised indication, for a medicine or medical device with a market authorisation, means a purpose or an indication for which it is authorised as set out in its market authorisation (*see* section 129(1)(c))

biologic is defined in section 33

biologic component is defined in section 33

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

civil penalty is defined in section 274

civil penalty order means an order made under section 274

civil penalty proceedings means proceedings against a person for a civil penalty contravention (*see* subpart 4 of Part 8)

clinical trial is defined in section 37

communication is defined in section 196

complying prescription is defined in section 54

complying standing order is defined in section 55

compound is defined in section 38

consumer information means information about a therapeutic product that is intended as information for patients, consumers, or end-users of the product

controlled activity is defined in section 70

critical-needs product is defined in section 35

Crown organisation has the same meaning as in section 4 of the Crown Organisations (Criminal Liability) Act 2002

custom health benefit claim is defined in section 62

custom-made device is defined in section 25

Customs has the same meaning as in section 5 of the Customs and Excise Act 2018 (*see also* the definition of **subject to the control of Customs**)

device production system is defined in section 25

directions order is defined in section 223

dispense is defined in section 39

distribute, in relation to an advertisement, is defined in section 196

enforceable undertaking means an undertaking that has been accepted by the Regulator under section 294 and is in force

enforcement purposes is defined in section 242

ethics approval means an approval granted by an ethics approval entity

ethics approval entity means any of the following:

(a) a committee established under section 92(1) and (3)(a) of the Pae Ora (Healthy Futures) Act 2022:

(b) the Ethics Committee established under section 24 of the Health Research Council Act 1990:

(c) a committee approved by the Ethics Committee under section 25(1)(c) of the Health Research Council Act 1990:

(d) a person or body that—

(i) performs functions similar to those of the committees referred to in paragraphs (a) to (c); and

(ii) the Regulator, by Regulator's notice, says is an ethics approval entity

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

export is defined in section 40

export authorisation means a market authorisation of the kind described in section 120(1)(c)

export standards is defined in section 60

fit and proper person means a person who the Regulator has determined to be a fit and proper person in accordance with section 61

general-sale medicine is defined in section 23

grounds to cancel, in relation to a market authorisation, is defined in section 139

grounds to suspend or cancel, in relation to a licence or permit, is defined in section 172 or 173

health benefit claim is defined in section 62

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, in relation to a medicine, means a health practitioner whose scope of practice includes prescribing the medicine

import is defined in section 41

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

infringement fee is defined in section 280

infringement notice is defined in section 280

infringement offence is defined in section 280

innovative medicine application is defined in section 151

inspector means—

(a) a person appointed under section 356; or

(b) the Regulator

intended for use is defined in section 17

label means a label, marking, writing, illustration, or other means of displaying or providing information

licence means a licence granted under section 159

licensed place is defined in section 155

licensee means the holder of a licence

limitation includes a prohibition, restriction, or condition

low-concentration NHP is defined in section 32

major change is defined in section 132

manufacture is defined in sections 42, 44, 45, 48, and 49

manufacturer is defined in section 42

market authorisation means an authorisation issued by the Regulator under section 121 or 126

medical device is defined in section 24

medicine is defined in section 22

medicine access limitation order is defined in section 230

medicine that requires compounding is defined in section 38

Minister means the Minister of the Crown who, under the authority of a warrant or with the authority of the Prime Minister, is responsible for the administration of this Act

Ministry means the department of State that, with the authority of the Prime Minister, is for the time being responsible for the administration of this Act

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

New Zealand means the land and waters enclosed by the outer limits of the territorial sea of New Zealand (as described in section 3 of the Territorial Sea, Contiguous Zone, and Exclusive Economic Zone Act 1977)

NHP (which is an acronym of natural health product) is defined in section 29

NHP ingredient is defined in section 30

non-wholesale supply is defined in section 57

notify means to give notice in writing to a person and, if it is the Regulator being notified, in accordance with section 387

off-label use is defined in section 50

opportunity to comment is defined in section 362

original decision is defined in section 373

overseas organisation means an overseas or international organisation whose functions or activities relate 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 is defined in section 229

patient, in relation to a veterinarian, means an animal under the care of the veterinarian (*see also* section 56(5) in relation to supplying a product to a patient that is an animal)

patient-matched device is defined in section 25

permit means a permit granted under section 167

permit holder means the holder of a permit

permitted health benefit claim is defined in section 62

person includes a Crown organisation that section 6 requires to be treated as a separate legal personality

person in the supply chain is defined in section 58

personal information has the same meaning as in section 7 of the Privacy Act 2020

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

pharmacist medicine is defined in section 23

pharmacy activity is defined in section 51

pharmacy business is defined in section 51

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

pharmacy licence requirements is defined in section 52

pharmacy medicine is defined in section 23

pharmacy worker is defined in section 53

place, in subpart 2 of Part 7 and subpart 1 of Part 8, includes a vehicle as defined in section 3(1) of the Search and Surveillance Act 2012

practitioner regulatory body means—

(a) a responsible authority under the Health Practitioners Competence Assurance Act 2003; or

(b) the Veterinary Council of New Zealand

premises restriction order is defined in section 219

prepare for administration is defined in section 36

prepare for use, in relation to a medical device, is defined in section 59

prescribe, in relation to a medicine, is defined in section 54

prescription is defined in section 54

prescription API is defined in section 28

prescription medicine is defined in section 23

product information means information about a therapeutic product that is intended as information for health practitioners or other persons in the supply chain

product moratorium order is defined in section 225

product standards is defined in section 64

prohibited product is defined in section 34

prohibited product order is defined in section 227

protected active ingredient information is defined in section 151

protection period is defined in section 152

provisional authorisation means a market authorisation of the kind described in section 120(1)(b)

publicly available is defined in section 388

qualified, in relation to a pharmacy worker, is defined in section 53

recall order is defined in section 217

recognised NHP ingredient is defined in section 30

recognised prescriber, in relation to a medicine, means—

(a) a health practitioner prescriber for the medicine; or

(b) a veterinarian; or

(c) any other person who is allowed by a licence, permit, or provision of subpart 3 of Part 3 to prescribe the medicine

regulations means regulations made under section 390

Regulator means the Therapeutic Products Regulator under section 337

Regulator's notice means a notice made under section 393

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

regulatory order means any of the following:

(a) an advertising remediation order:

(b) a directions order:

(c) a medicine access limitation order:

(d) a premises restriction order:

(e) a product moratorium order:

(f) a prohibited product order:

(g) a recall order

regulatory purposes is defined in section 208

reportable product is defined in section 35

responsible manufacturer is defined in section 43

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

rongoā advisory committee means the rongoā advisory committee under section 365

rongoā product is defined in section 31

rules means rules made by the Regulator under section 392

scope of practice, in relation to a health practitioner, means their scope of practice under the Health Practitioners Competence Assurance Act 2003

senior manager is defined in section 65

software as a medical device is defined in section 26

special-case requirement is defined in section 66

sponsor, in relation to a medicine, a medical device, or an NHP with a market authorisation, means—

(a) the person to whom the market authorisation was issued under section 121 or 126; or

(b) if the market authorisation has been transferred under section 133, the person to whom it was transferred; or

(c) in Part 7 or 8, a person who is taken to be the sponsor under section 205 or 241 respectively

standard authorisation means a market authorisation of the kind described in section 120(1)(a)

standard health benefit claim is defined in section 63

standing order is defined in section 55

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

subject to the control of Customs has the same meaning as in section 6 of the Customs and Excise Act 2018

supply is defined in section 56

supply chain activity is defined in section 58

supply-restricted device is defined in section 27

tamper with is defined in section 190

therapeutic product is defined in section 16

therapeutic purpose is defined in section 15

this Act includes the regulations, rules, and Regulator's notices

use, in relation to a medical device, is defined in section 59

use-restricted device is defined in section 27

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

wholesale supply is defined in section 57

work is defined in section 67.

Guidance note

The definition of a term in this Act does not affect the meaning of that term in any other Act.

Subpart 2—Therapeutic products

15 Therapeutic purposes

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) investigating a human physiological process:

(h) supporting or sustaining human life:

(i) providing vitamin, mineral, or other human nutritional supplementation:

(j) maintaining or promoting human health:

(k) disinfecting medical devices:

(l) a purpose connected with a purpose referred to in paragraphs (a) to (k).

16 Therapeutic product

(1) Each of the following is a **therapeutic product**:

(a) a product that is intended for use in, on, or in relation to humans for a therapeutic purpose:

(b) a product that regulations referred to in section 19(1) say is a therapeutic product:

(c) a product that is intended for use as an active ingredient of a medicine.

(2) If 2 or more products—

(a) are intended by the manufacturer to be used together; and

(b) when used together, meet the definition in subsection (1),—

those products together are a single therapeutic product (even if some or all of them separately would not be therapeutic products).

Example

A first aid kit consisting of a bag and its contents, some of which are medicines or medical devices, would be a single therapeutic product under subsection (2).

(3) A product is not a therapeutic product under subsection (1)(a) if—

(a) it is a food, as defined in section 9 of the Food Act 2014 (but disregarding section 9(1)(c)(iii)); and

(b) there is an adopted joint food standard in force under the Food Act 2014 that is applicable to the product; and

(c) if it were a therapeutic product it would be an NHP.

(4) A product is not a therapeutic product if regulations referred to in section 19(2) say it is not.

17 Intended for use for therapeutic purpose

(1) Something is **intended for use** in, on, or in relation to humans 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 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.

(2) However, something is not intended for that use if it is intended primarily for another purpose and its therapeutic purpose is merely incidental to that primary purpose.

Example

If flour intended for human consumption as a food is fortified with folic acid, the flour is, to some extent, intended for the therapeutic purpose of providing vitamin

supplementation. However, that is merely incidental to the flour's primary purpose of being a food. Therefore, the flour would be food and not a therapeutic product.

18 Naturally occurring thing may be product

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.

Example

Human blood is not generally regarded as a product. However, if a person donates blood to the New Zealand 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.

19 Regulations affecting meaning of therapeutic product

(1) The Minister must not recommend that regulations be made about a product for the purposes of section 16(1) unless satisfied on reasonable grounds that—

(a) the product is of the same general nature as a therapeutic product or therapeutic products in general; and

(b) the likely risks associated with the product are of the same general nature as those associated with therapeutic products; and

(c) carrying on controlled activities or supply chain activities with the product is not otherwise adequately regulated; and

(d) in all the circumstances it is appropriate for the product to be regulated under this Act as a therapeutic product.

(2) The Minister must not recommend that regulations be made about a product for the purposes of section 16(4) unless satisfied on reasonable grounds that—

(a) either—

(i) the product is adequately regulated by other means; or

(ii) the likely risks associated with the product are low enough that regulation of it is not necessary; and

(b) in all the circumstances it is appropriate for the product not to be regulated under this Act.

20 Types of therapeutic products

A therapeutic product is one of the following:

(a) a medicine:

(b) a medical device:

(c) an API:

(d) an NHP.

21 Changing or clarifying type of therapeutic product

(1) If a therapeutic product meets the definitions of 2 or more types of therapeutic products, the rules may say which of those types of product it is.

(2) If it is unclear whether a therapeutic product is a medicine, medical device, API, or NHP, the rules may say which type of therapeutic product it is.

(3) If a therapeutic product would otherwise be a medicine, medical device, API, or NHP, the rules may say it is a different type of therapeutic product.

(4) The Regulator must not make rules for the purposes of subsections (1) to (3) unless satisfied on reasonable grounds that the product will be most appropriately regulated if it is treated as a product of the kind the rules say it is (*see also* section 392(2)).

(5) The Regulator may, by Regulator's notice, say that a specific NHP is a medicine if—

(a) the sponsor of the NHP (or if there is no sponsor, a person who meets the criteria in section 128 for being a sponsor) applies for the notice to be made; and

(b) the Regulator is satisfied on reasonable grounds that it is appropriate for the product to be regulated as a medicine.

Guidance note

Decisions under subsection (5) are reviewable under subpart 6 of Part 9.

Medicines

22 Medicine

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

(a) is a therapeutic product under section 16(1)(a) or (b); and

(b) achieves, or is likely to achieve, its principal intended action by pharmacological, immunological, metabolic, or genetic means.

(2) A therapeutic product is also a **medicine** if the rules or a Regulator's notice referred to in section 21 say it is.

(3) However, a product referred to in subsection (1) is not a medicine if—

(a) it is an NHP; or

(b) the rules referred to in section 21 say it is a different type of therapeutic product.

23 Classes of medicine

(1) A medicine is one of the following:

(a) a prescription medicine:

(b) a pharmacist medicine:

(c) a pharmacy medicine:

(d) a general-sale medicine.

(2) The regulations must provide for the classification of medicines by setting criteria by which medicines are to be classified.

(3) The rules must classify medicines by describing the classes of medicines that are prescription medicines, pharmacist medicines, pharmacy medicines, and general-sale medicines.

(4) A medicine is—

(a) a **prescription medicine** if it is a medicine that—

(i) is in a class of medicines that the rules say are prescription medicines; or

(ii) is not in any of the classes of medicines described in the rules made for the purposes of subsection (3):

(b) a **pharmacist medicine** if it is a medicine that is in a class of medicines that the rules say are pharmacist medicines:

(c) a **pharmacy medicine** if it is a medicine that is in a class of medicines that the rules say are pharmacy medicines:

(d) **general-sale medicine** if it is a medicine that is in a class of medicines that the rules say are general-sale medicines.

Medical devices

24 Medical device

(1) A therapeutic product is a **medical device** if it—

(a) is a therapeutic product under section 16(1)(a) or (b); and

(b) achieves, or is likely to achieve, its principal intended action by means other than pharmacological, immunological, metabolic, or genetic means (although its function may be assisted by pharmacological, immunological, metabolic, or genetic processes).

(2) A therapeutic product is also a **medical device** if the rules referred to in section 21 say it is.

(3) However, a product referred to in subsection (1) is not a medical device if the rules referred to in section 21 say it is a different type of therapeutic product.

25 Patient-matched devices, custom-made devices, and device production systems

(1) A medical device is a **patient-matched device** if it—

(a) is manufactured using a standard production process but each device is produced for a specific patient to match their morphology and circumstances (including a device referred to in section 46(2)); and

(b) meets any criteria in the rules for being a patient-matched device.

(2) A medical device is a **custom-made device** if it—

(a) is manufactured on a case-by-case basis to meet the needs of a specific patient but is not a patient-matched device (including a device referred to in section 46(3)); and

(b) meets any criteria in the rules for being a custom-made device.

(3) A **device production system** is a system (consisting of hardware, software, and the raw materials used in producing devices) that—

(a) is intended to be used in health care settings to produce a patient-matched device; and

(b) meets any criteria in the rules for being a device production system.

(4) If it is unclear whether a device is a patient-matched device or custom-made device, the rules may say whether it is.

(5) If it is unclear whether something is, or is part of, a device production system, the rules may say whether it is.

26 Software as a medical device

(1) **Software as a medical device** means software that meets the definition of a therapeutic product without any associated hardware (other than an unrelated device that is needed solely to present a user interface).

(2) Software is also **software as a medical device** if—

(a) it is intended to be used to augment another product that is not a therapeutic product by making use of the functions, sensors, or other components of that product; and

(b) the product and software together meet the definition of a therapeutic product.

(3) The other product referred to in subsection (2) is not a therapeutic product merely because the software as a medical device can be used to augment it.

(4) Software that is a component part of another product that is a medical device—

(a) is not itself software as a medical device; and

(b) is subject to this Act as a component part of the other product.

(5) If it is unclear whether software is software as a medical device, the rules may say whether it is.

27 Supply-restricted devices and use-restricted devices

(1) A medical device is a **supply-restricted device** if the rules—

(a) say it is a supply-restricted device; and

(b) set out restrictions that apply to the non-wholesale supply of the device.

(2) A medical device is a **use-restricted device** if the rules—

(a) say it is a use-restricted device; and

(b) set out restrictions that apply to the use of the device.

(3) Supply or use restrictions may (without limitation) relate to any of the following:

(a) the persons who are allowed to supply or use the device:

(b) the circumstances in which the device is allowed to be supplied or used:

(c) how the device is allowed to be supplied or used.

(4) The restrictions on supply may prohibit non-wholesale supply of a medical device.

APIs

28 API and prescription API

(1) API is an acronym of active pharmaceutical ingredient.

(2) A therapeutic product is an **API** if—

(a) it is a therapeutic product under section 16(1)(c); or

(b) the rules referred to in section 21 say it is.

(3) However, a product referred to in subsection (2)(a) is not an API if the rules referred to in section 21 say it is a different type of therapeutic product.

(4) An API is a **prescription API** if any medicine in which it is the only API is (or, if manufactured, would be) a prescription medicine.

NHPs

29 NHP

(1) NHP is an acronym of natural health product.

(2) A therapeutic product is an **NHP** if—

(a) it is a therapeutic product under section 16(1)(a) or (b); and

(b) it consists of 1 or more of the following and nothing else:

(i) NHP ingredients:

(ii) additives or formulation aids that the rules say are permitted for use in NHPs; and

(c) the concentration of each NHP ingredient is not more than the maximum concentration set out in the rules.

(3) However, a product referred to in subsection (2) is not an NHP if—

(a) it is intended to be administered by injection or parenteral infusion; or

(b) the rules or a Regulator's notice referred to in section 21 say it is a different type of therapeutic product.

(4) A therapeutic product is also an **NHP** if—

(a) the rules referred to in section 21 say it is; or

(b) it is a low-concentration NHP under section 32(2).

30 NHP ingredient, recognised NHP ingredient, and additive or formulation aid

(1) Each of the following is an **NHP ingredient**:

(a) a plant, plant material, an alga, a fungus, or non-human animal material:

(b) a substance or mixture of substances that—

(i) is obtained by expression, extraction, distillation, purification, or a traditional preparation of anything referred to in paragraph (a); and

(ii) is not subject to any other process involving chemical transformation other than hydrolysis, electrolysis, or a process specified in the rules:

(c) a vitamin or provitamin, including salts and other compounds, of the following types:

(i) biotin:

(ii) choline:

(iii) folate:

(iv) vitamin A, B1, B2, B3, B5, B6, B12, C, D, E, or K:

(d) a mineral or mineral compound:

(e) an amino acid:

(f) a micro-organism, whole or extracted:

(g) a synthetic equivalent of a substance referred to in paragraphs (b) to (e):

(h) anything else that the rules say is an NHP ingredient.

(2) An NHP ingredient is a **recognised NHP ingredient** if the rules say it is.

(3) Each of the following is an **additive or formulation aid**:

(a) a preservative, antioxidant, colouring, flavouring, or sweetener:

(b) a substance that is included in a product—

(i) as a carrier for the product's active ingredients; or

(ii) to modify the pH, viscosity, or handling properties of the product during its manufacture; or

(iii) as a vehicle for the product's administration.

31 Rongoā

(1) Sections 112, 355, and 365 to 369, and related provisions recognise and respect the Crown's obligations to give effect to the principles of te Tiriti o Waitangi/the Treaty of Waitangi in relation to rongoā.

(2) An NHP is a **rongoā product** if it—

(a) is manufactured by a rongoā practitioner; and

(b) is intended for use in a rongoā service or activity.

(3) A service or activity provided by a rongoā practitioner may be a rongoā service or activity whether or not the practitioner is (or is entitled to be) paid or given something in exchange for providing it.

(4) A person is an **associate** of a rongoā practitioner if the person—

(a) works for the practitioner; or

(b) is otherwise involved (in any capacity) in delivering a rongoā service or activity provided by the practitioner.

32 Low-concentration NHP

(1) An NHP is a **low-concentration NHP** if—

(a) it is an NHP under section 29(2) or (4)(a); and

(b) the concentration of every ingredient in it (other than an additive or a formulation aid) is not more than 20 parts per million (or any lower concentration set out in the rules); and

(c) it does not contain anything of human origin; and

(d) it does not contain anything that is, or is derived from, an animal or part of an animal set out in the rules; and

(e) it is not intended to be administered by injection or parenteral infusion or to the eye.

(2) A therapeutic product is also a **low-concentration NHP** if—

(a) it is a therapeutic product under section 16(1)(a) or (b); and

(b) it contains 1 or more ingredients (other than an additive or formulation aid) that are not NHP ingredients; and

(c) it meets all the criteria in subsection (1)(b) to (e).

(3) However, a product is not a low-concentration NHP under subsection (2) if the rules say it is not.

Other terms relating to therapeutic products

33 Biologic and biologic component

(1) A medicine, a medical device, or an API is a **biologic** if it is or contains a biologic component.

(2) **Biologic component** means any of the following (whether living or not):

(a) human or non-human cells (including blood, tissues, and whole organs) and subcellular components of them:

(b) micro-organisms (including bacteria, viruses, and mycoplasma) and components of them:

(c) material that is derived from anything referred to in paragraph (a) or (b) (whether modified, engineered, or otherwise):

(d) anything that is synthesised or manufactured for the purpose of having the same effect anything referred to in paragraphs (a) to (c).

(3) However, a product referred to in subsection (1) is not a biologic if the rules say that it is not.

(4) If it is unclear whether a product is a biologic, the rules may say whether it is.

(5) Something that is the product of something referred to in subsection (2)(a) or (b) is not a biologic component.

34 Prohibited product

(1) A therapeutic product is a **prohibited product** if the regulations say it is.

(2) The Minister must not recommend that regulations be made about a product for the purposes of subsection (1) unless satisfied on reasonable grounds that—

(a) the product directly or indirectly exposes any individual to a risk of death, serious injury, or serious illness; and

(b) the risk cannot be adequately managed by the exercise of the Regulator's powers under this Act.

35 Reportable products and critical-needs products

(1) A medicine or medical device with a standard authorisation or provisional authorisation is a **reportable product** if the rules say it is.

(2) The Regulator must not make rules about a product for the purposes of subsection (1) unless—

(a) the product is on the pharmaceutical schedule (as defined in section 4 of the Pae Ora (Healthy Futures) Act 2022); or

(b) the Regulator is satisfied on reasonable grounds that—

(i) the product is critical to the health of persons in New Zealand; and

(ii) it would be in the interests of public health for the Regulator to be notified of any likely shortage of the product or any decision of the sponsor to cease importing or supplying it.

(3) A medicine or medical device is a **critical-needs product** if it is a reportable product and the rules say it is a critical-needs product.

(4) The Regulator must not make rules about a product for the purposes of subsection (3) unless satisfied on reasonable grounds that—

(a) there is no therapeutic product with a market authorisation that could reasonably be used as a substitute for the product; and

(b) a shortage of the product will expose any individual to a risk of death, serious injury, or serious illness.

Subpart 3—Activities

36 Administer and prepare for administration

(1) To **administer** a medicine or an NHP means to do either or both of the following:

(a) administer it 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:

(b) prepare it for that administration.

(2) To **prepare for administration**, in relation to a medicine or an NHP, includes either or both of the following:

(a) to dissolve, disperse, dilute, or mix it in or with another substance as an administration medium:

(b) to mix it with another medicine or NHP that is to be administered at the same time.

37 Clinical trial

(1) A **clinical trial** of a medicine or medical device means an investigation—

(a) that involves administering the medicine to, or using the device on, 1 or more individuals (**participants**); and

(b) that is undertaken to obtain information about,—

(i) if the trial is of a medicine, its safety or efficacy by doing any 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:

(ii) if the trial is of a medical device, its safety or performance; and

(c) to which any of the following apply:

(i) the assignment of each participant 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 participant in the trial:

(iii) diagnostic or monitoring procedures additional to those used in normal clinical practice are applied to the participant.

(2) However, the following activities are not part of a clinical trial (for the purposes of this Act):

(a) preparatory activities (such as recruiting participants) carried out before activities intended to obtain the information referred to in subsection (1)(b) begin:

(b) post-investigation activities carried out after the information has been obtained.

(3) If it is unclear whether an activity is part of a clinical trial or one to which subsection (2) applies, the rules may say it is one or the other.

38 Compound and medicine that requires compounding

Compound

(1) To **compound** a medicine means to produce a quantity of it ready for supply directly to a patient (or to the patient's health practitioner or veterinarian) in response to a request for that supply.

(2) Compounding a medicine is part of manufacturing it (*see* section 44).

Medicine that requires compounding

(3) A medicine is a **medicine that requires compounding** if it does not have a market authorisation and needs to be compounded for each patient.

(4) However, a medicine is not a medicine that requires compounding if—

(a) it is a biologic medicine; or

(b) an application for a market authorisation for the medicine has been refused.

39 Dispense

(1) To **dispense** a medicine means to bring it to a state ready for immediate supply to a specific patient in response to a request for that supply.

(2) Preparing a medicine for administration is not dispensing.

Example

Dispensing a medicine might include the following—

- removing the quantity of the medicine required by the patient from a container sold by wholesale and packaging it in a container suitable to be given to the patient:
- labelling the medicine with the patient's name and dosage details:
- ensuring that any necessary consumer information is included with the medicine.

40 Export

(1) To **export** a therapeutic product means—

(a) to send or take it out of New Zealand; or

(b) in the case of software as a medical device that is manufactured in New Zealand, to make it available to persons outside New Zealand.

(2) However, a therapeutic product that was not manufactured in New Zealand is not exported if—

(a) it was brought into New Zealand for the purpose of being sent or taken out of New Zealand without being released into the supply chain in New Zealand; and

(b) it remains subject to the control of Customs at all times until it is sent or taken out of New Zealand.

(3) If a therapeutic product is exported, it is taken to have been exported by each person who is its exporter (as defined in section 5 of the Customs and Excise Act 2018).

41 Import

(1) To **import** a therapeutic product means—

(a) to bring it into New Zealand; or

(b) in the case of software as a medical device that is manufactured outside New Zealand, to make it available for use by persons in New Zealand.

(2) However, a therapeutic product is not imported if—

(a) it is brought into New Zealand for the purpose of being taken or sent out of New Zealand without being released into the supply chain in New Zealand; and

(b) it remains subject to the control of Customs at all times until it is taken or sent out of New Zealand.

(3) If a therapeutic product is imported, it is taken to have been imported by each person who is its importer (as defined in section 5 of the Customs and Excise Act 2018).

42 Manufacture and manufacturer

(1) To **manufacture** a therapeutic product is defined in,—

(a) if the product is a medicine, section 44:

(b) if the product is a medical device, section 45:

(c) if the product is an API, section 48:

(d) if the product is an NHP, section 49.

(2) A person is a **manufacturer** of a therapeutic product if they do anything that is part of its manufacture.

(3) However, if the product is a medical device produced using a device production system, this section is subject to section 46.

43 Responsible manufacturer

(1) The **responsible manufacturer** of a therapeutic product is the person who is primarily responsible for its manufacture.

(2) Who is primarily responsible for manufacturing a therapeutic product depends on all of the circumstances, including the following:

- (a) who transforms the starting materials into the final product:
- (b) who initiated its manufacture:
- (c) who is responsible for overall quality assurance and quality control in its manufacture:
- (d) if it is, or is intended to be, released into the supply chain, whose name or trade mark it is, or is to be, supplied under.

(3) A person may be the responsible manufacturer of a product whether or not they do anything that is part of its manufacture.

(4) The matters referred to in subsection (2)—

- (a) are relevant but not determinative considerations; and
- (b) do not limit the matters that may be considered in determining who is the responsible manufacturer of a product.

(5) However, if the product is a medical device produced using a device production system, this section is subject to section 46.

(6) If a medical device is remanufactured, the person who is the responsible manufacturer changes (*see* section 47).

44 Manufacture of medicine

(1) To **manufacture** a medicine means to do any of the following:

- (a) produce it:
- (b) do anything that is part of the process of—
  - (i) producing it:
  - (ii) bringing it to its final state (including, for example, testing, sterilising, packing, or labelling it, or releasing it for supply):
- (c) in the case of a biologic medicine,—
  - (i) procure the biologic component (including removing it from its natural state so as to make it into a product (*see* section 18)):
  - (ii) test, modify, engineer, or otherwise process the biologic component:
  - (iii) preserve, bank, or otherwise store the biologic component.

(2) Compounding a medicine is part of its manufacture.

(3) Dispensing a medicine is not part of its manufacture.

(4) Preparing a medicine for administration is not part of its manufacture 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, a recognised prescriber for the medicine.

Guidance note

Preparing a medicine for administration is part of administering it (*see* section 36).

45 Manufacture of medical device

(1) To **manufacture** a medical device means to do any of the following:

(a) produce it:

(b) do anything that is part of the process of—

(i) producing it:

(ii) bringing it to its final state (including, for example, testing, sterilising, packing, or labelling it, or releasing it for supply):

(c) in the case of a biologic device,—

(i) procure the biologic component (including removing it from its natural state so as to make it into a product (*see* section 18)):

(ii) test, modify, engineer, or otherwise process the biologic component:

(iii) preserve, bank, or otherwise store the biologic component:

(d) in the case of software as a medical device or a device that includes software, do anything that is part of developing the software:

(e) in the case of a remanufactured device, do anything that is part of the process of remanufacturing it (*see* section 47).

(2) If a medical device is supplied by its responsible manufacturer as being in its final state but needs to be prepared for use, preparing it is not part of manufacturing the device as long as the preparation—

(a) is done in accordance with the responsible manufacturer's product information; and

(b) does not constitute remanufacturing the device.

(3) However, if the product is a medical device produced using a device production system, this section is subject to section 46.

Guidance note

Preparing a device for use is part of using the device (*see* section 59).

46 Manufacturer of medical device produced using device production system

(1) If a medical device is produced using a device production system, subsection (2) applies to the device if—

(a) the device is produced by a person who is allowed by a licence, permit, or provision of subpart 3 of Part 3 to do so; and

(b) the device is produced in a health care setting for a specific patient; and

(c) before producing the device, the person doing so takes reasonable steps to ensure that—

(i) the system is functioning correctly; and

(ii) any upgrades, software updates, or other changes to the system that its manufacturer has notified the owner of the system need to be made have been made; and

(d) the device is produced in accordance with—

(i) the system's manufacturer's instructions for using the system; and

(ii) any requirements in the rules about how the device is to be produced.

(2) If this subsection applies,—

(a) the medical device is a patient-matched device; and

(b) the person using the system to produce the device is not a manufacturer of the device; and

(c) the system's manufacturer is the manufacturer, and responsible manufacturer, of the device; and

(d) the manufacturing of the medical device by the system's manufacturer referred to in paragraph (c) is taken to include—

(i) manufacturing the system; and

(ii) using the system to produce the medical device; and

(e) the system's manufacturer is taken to have supplied the device to the person who produced it when it was produced.

(3) If a medical device is produced using a device production system and subsection (2) does not apply,—

(a) the device is a custom-made device; and

(b) the system's manufacturer is not a manufacturer of the device; and

(c) the person using the system to produce the device is the manufacturer, and responsible manufacturer, of the device; and

(d) manufacturing the medical device—

(i) includes using the system to produce the medical device; but

(ii) does not include manufacturing the system.

(4) In this section,—

(a) the **manufacturer** of a device production system is the person who would be the responsible manufacturer of the system under section 43 (other than section 43(5)) if the system were a medical device; and

(b) to **manufacture** a device production system means to do anything that would be part of manufacturing the system (under section 45) if the system were a medical device.

47 Remanufacture of medical device

(1) If a medical device has been supplied by its responsible manufacturer as being in its final state, to **remanufacture** it means to make a major change to it by doing any of the following:

(a) changing the purpose for which it is intended to be used:

(b) enabling it to be used in a way that is materially different from that intended by the responsible manufacturer of the original device:

(c) if it was originally manufactured as a single-use-only device, enabling it to be reused:

(d) making it into a different medical device:

(e) otherwise altering, refurbishing, reconditioning, or further processing the device.

(2) If a medical device is intended to be reused, a person does not remanufacture the device merely by sterilising it, cleaning it, carrying out repairs and maintenance, updating software or other components of the device, or undertaking similar processes, for the purpose of—

(a) enabling its continued use in the originally intended manner; or

(b) upgrading it to incorporate minor changes that are within the scope of the device's market authorisation under section 131.

(3) Despite subsection (1)(d), if—

(a) the responsible manufacturer of a medical device (the **original device**) makes a major change that results in a different device (*see* section 132); and

(b) a market authorisation is issued for the new device,—

a person does not remanufacture one of the original devices merely by upgrading it to incorporate the major change (and thus make it into a different device), provided that they do so in accordance with the instructions of the responsible manufacturer.

Change of responsible manufacturer

(4) If a medical device is remanufactured,—

(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.

48 Manufacture of API

To **manufacture** an API means to do any of the following:

(a) produce it:

(b) do anything that is part of the process of—

(i) producing it:

(ii) bringing it to its final state ready for use in the manufacture of medicines (including, for example, testing, sterilising, packing, or labelling it, or releasing it for supply):

(c) in the case of a biologic API,—

(i) procure the biologic component (including to remove it from its natural state so as to make it into a product (*see* section 18)):

(ii) test, modify, engineer, or otherwise process the biologic component:

(iii) preserve, bank, or otherwise store the biologic component.

49 Manufacture of NHP

To **manufacture** an NHP means to do any of the following:

(a) produce it:

(b) do anything that is part of the process of—

(i) producing it:

(ii) bringing it to its final state (including, for example, testing, sterilising, packing, or labelling it, or releasing it for supply):

(c) in relation to an NHP ingredient,—

(i) procure it (including removing it from its natural state so as to make it into a product (*see* section 18)):

(ii) prepare it by expression, extraction, distillation, purification, or a traditional preparation method:

(iii) process it by any of the processes referred to in section 30(1)(b)(ii).

50 Off-label use

A person carrying on a controlled activity with a medicine or medical device that has a standard authorisation or provisional authorisation for 1 or more authorised indications carries on the activity for an **off-label use** if,—

(a) in carrying on the activity, they supply, administer, or use the medicine or device for a purpose or an indication that is not an authorised indication; or

(b) they carry on the activity for the purpose of enabling such supply, administration, or use.

Guidance note

A medicine or medical device with a standard authorisation or provisional authorisation is authorised only for its authorised indications (*see* section 131). Supplying, administering, or using it for a different purpose or indication constitutes supplying, administering, or using a product that does not have a standard authorisation or provisional authorisation. Therefore, a person is allowed to supply, administer, or use it for an off-label use only if they are allowed to do so with products that do not have a standard authorisation or provisional authorisation.

51 Pharmacy business and pharmacy activity

(1) A business or undertaking is a **pharmacy business** if its activities include any of the following:

(a) compounding medicines for non-wholesale supply:

(b) dispensing medicines for non-wholesale supply:

(c) supplying prescription medicines or pharmacist medicines by non-wholesale supply.

(2) However, a business or undertaking is not a pharmacy business if—

(a) it is the professional practice of a health practitioner or veterinarian who is allowed to dispense or supply medicines by a provision of subpart 3 of Part 3; or

(b) it is a business or undertaking of a kind that the regulations say is not a pharmacy business.

(3) If a business or undertaking is a pharmacy business under subsection (1), the pharmacy business is taken to include all of the following (**pharmacy activities**) that are carried on by the business or undertaking:

(a) the activities referred to in subsection (1):

(b) supplying pharmacy medicines by non-wholesale supply:

(c) supplying medicines or medical devices by wholesale supply, if that is allowed by section 82:

(d) exporting or importing medicines or medical devices, if that is allowed by section 80 or 81.

(4) If the business or undertaking also carries on other activities (including supplying general-sale medicines), those activities are not part of the pharmacy business.

Guidance note

A pharmacy licence covers the pharmacy activities carried on by the pharmacy business. It does not cover activities that are not part of the pharmacy business.

52 Pharmacy licence requirements

The **pharmacy licence requirements** for a pharmacist carrying on 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) set out in the licence as one at which the activity is allowed to be carried on; or

(ii) at which the rules say the activity may be carried on; and

(c) otherwise complies with the licence.

53 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 with a medicine if they meet the qualification, training, and competency requirements in the regulations for carrying on that pharmacy activity with that medicine.

54 Prescription, complying prescription, and prescribe

(1) A **prescription** is a direction that sets out details of a specific medicine that is to be administered by or to a specific patient.

(2) A prescription for a medicine is a **complying prescription** if it is issued—

(a) by a person who is allowed to issue it; and

(b) in accordance with any requirements in the rules about issuing prescriptions.

(3) It ceases to be a complying prescription if an expiry event set out in the rules occurs.

(4) To **prescribe** a medicine means to issue a prescription for that medicine.

(5) A prescription may be issued orally, in writing, or in any other form, unless the rules say otherwise.

(6) A person does not issue a prescription merely by doing either or both of the following:

(a) making a record of a prescription that was issued orally:

(b) after dispensing or supplying some but not all of the medicine specified in a prescription, making a record of the medicine that remains to be supplied.

(7) Rules made for the purposes of subsection (2) may (without limitation) relate to any of the following:

(a) the circumstances in which a prescription is allowed to be issued:

(b) the form of a prescription:

(c) the content of a prescription:

(d) how a prescription is issued.

55 Standing order and complying standing order

(1) A **standing order** is an order that allows a person to do any of the following with a medicine with a standard authorisation or provisional authorisation:

(a) in the case of a prescription medicine,—

(i) supply it by non-wholesale supply for an authorised indication and without a prescription:

(ii) administer it for an authorised indication:

(b) in the case of a pharmacist medicine or pharmacy medicine, supply it by non-wholesale supply for an authorised indication.

(2) A standing order is a **complying standing order** if—

(a) it is issued by a person who is allowed to issue it; and

(b) it is issued in accordance with any requirements in the rules about issuing standing orders.

(3) A complying standing order—

(a) takes effect when it is issued; and

(b) remains in force until—

(i) it expires (if it has an expiry date); or

(ii) it is revoked by the issuer; or

(iii) it is revoked by the occurrence of a revocation event set out in the rules.

(4) However, a complying standing order has effect subject to any requirements in the rules about when a standing order takes effect or ceases to be in force.

(5) For the purposes of subpart 9 of Part 8, a person who is allowed by a complying standing order to do something is taken to be the agent of the person who issued the order.

(6) Rules made for the purposes of subsection (2) may (without limitation) relate to any of the following:

(a) the circumstances in which a standing order is allowed to be issued:

(b) whether a standing order may be issued by a person in their capacity as the holder of a particular office or position:

(c) the form of a standing order:

(d) the content of a standing order:

(e) how a standing order is issued.

56 Supply

(1) To **supply** a therapeutic product means—

(a) to supply it to another person who is in New Zealand; or

(b) in the case of software as a medical device, to make it available for use by persons in New Zealand.

(2) Supply does not include administering a medicine or an NHP to, or using a medical device on, a patient.

(3) In determining whether a person has supplied a product, the following are immaterial:

(a) the quantity of it:

(b) the purpose for which it is supplied:

(c) whether the recipient pays for it or gives something in exchange for it, or is liable to do so:

(d) whether the recipient acquires legal title to it or only an entitlement to use it (for example, under a lease, hire-purchase, sharing agreement, software licence, or other arrangement):

(e) whether the supplier and recipient are in the same place at the same time:

(f) whether the supplier is in New Zealand:

(g) how it is supplied.

Supply to specific patient

(4) A person (the **supplier**) supplies a therapeutic product to a specific patient if the supplier supplies it—

(a) directly to the patient; or

(b) to a person who has lawful authority to receive it for the patient.

(5) 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.

Guidance note

For a medical device produced using a device production system, *see also* section 46(2)(e).

57 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, a medical device, or an NHP 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 it for any of the following purposes:

(a) to supply it to other persons in the course of the recipient's business or undertaking:

(b) to administer it to, or use it on, patients in the course of the recipient's business or undertaking:

(c) to use it in a scientific, educational, or commercial laboratory:

(d) to use it in a manufacturing or trade process.

(3) However, the supply of a medicine or medical device to a health practitioner is not wholesale supply if—

(a) the product is a medicine that requires compounding, a patient-matched device, or a custom-made device; and

(b) the recipient is a health practitioner of the patient for whom it was compounded or manufactured.

(4) Any supply of a medicine, a medical device, or an NHP that is not wholesale supply (for example, supply to patients or retail sale) is **non-wholesale supply**.

(5) For an API, any supply of the product is **wholesale supply**.

58 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 a business or undertaking and in circumstances that do not constitute carrying on a controlled activity:

(i) importing a therapeutic product:

(ii) exporting a therapeutic product:

(iii) supplying a therapeutic product:

(iv) being in possession of a therapeutic product:

(v) administering a medicine to a person or an animal:

(vi) administering an NHP to a person:

(vii) using a medical device on a person or an animal.

(2) However, an activity referred to in subsection (1)(b) is not a supply chain activity if the regulations say it is not.

(3) A person who carries on a supply chain activity is a **person in the supply chain**.

59 Use

(1) To **use** a medical device means to do any of the following:

(a) prepare it for use:

(b) use it for a therapeutic purpose in, on, or in relation to a person or an animal.

(2) To **prepare for use**, in relation to a therapeutic product, includes to do any of the following:

(a) assemble it:

(b) adjust it for a specific patient:

(c) calibrate, adjust, or otherwise prepare it before putting it into service.

Subpart 4—Other terms

60 Export standards

(1) The rules may set standards (**export standards**) for therapeutic products that are exported.

(2) The export standards may (without limitation) relate to any of the matters about which product standards may be made.

(3) The export standards may (without limitation) set standards for—

(a) particular products:

(b) products exported to a particular market:

(c) products that do not have a standard authorisation or provisional authorisation:

(d) products whose export authorisation allows them not to meet, or their sponsor not to comply with, a particular standard or requirement that would apply if the product were supplied in New Zealand.

(4) However, a provision of an export standard does not apply to a therapeutic product with a market authorisation—

(a) if the authorisation says it does not apply; or

(b) to the extent that meeting the standard would cause the product to not conform to its market authorisation.

61 Fit and proper person

(1) In determining whether a person (**person A**) is a fit and proper person for a particular purpose under this Act, the Regulator must have regard to the following:

(a) the purpose for which the determination is being made:

(b) any conviction of person A for—

(i) an offence against a relevant law; or

(ii) a crime involving dishonesty (as defined in section 2 of the Crimes Act 1961):

(c) any civil penalty order made against person A under a relevant law:

(d) 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:

(iv) any contravention by person A of—

(A) the authority; or

(B) a provision of a relevant law that applied to person A as the holder of the authority:

(e) whether there are other reasonable grounds to believe that person A is likely to contravene a provision of this Act:

(f) whether person A is or has been—

(i) bankrupt; or

(ii) subject to an insolvency event (as defined in section 6 of the Financial Markets Conduct Act 2013) or to an equivalent event under a law of another country:

(g) whether person A is of good character:

(h) any other matters that the Regulator thinks are relevant.

(2) In subsection (1)(a) to (g), a reference to person A includes a reference to each person—

(a) who is, or in the previous 7 years was, a senior manager of person A; or

(b) of whom person A is, or in the previous 7 years was, a senior manager.

(3) The Crown is taken to be a fit and proper person for all purposes under this Act (but to avoid doubt, this subsection does not apply to a Crown organisation).

(4) In this section, **relevant law** means any of the following Acts (or secondary legislation made under them):

(a) this Act:

(b) the Agricultural Compounds and Veterinary Medicines Act 1997:

(c) the Animal Products Act 1999:

(d) the Biosecurity Act 1993:

(e) the Customs and Excise Act 2018:

(f) the Fair Trading Act 1986:

(g) the Food Act 2014:

(h) the Hazardous Substances and New Organisms Act 1996:

(i) the Health Practitioners Competence Assurance Act 2003:

(j) the Human Assisted Reproductive Technology Act 2004:

(k) the Human Tissue Act 2008:

(l) the Misuse of Drugs Act 1975:

(m) the Pharmacy Ownership Act 1981:

(n) the Psychoactive Substances Act 2013:

(o) the Radiation Safety Act 2016:

(p) the Veterinarians Act 2005:

(q) any other New Zealand legislation that the regulations say is a relevant law:

(r) a law in another country that—

(i) the regulations say is a relevant law; or

(ii) corresponds to all or part of a law referred to in paragraphs (a) to (q):

(s) a law that was replaced by a law referred to in paragraphs (a) to (q).

62 Health benefit claim, permitted health benefit claim, and substantiating claims

(1) A claim about an NHP is a **health benefit claim** if it states or implies that the product is beneficial for a therapeutic purpose.

(2) A **permitted health benefit claim** for an NHP with a market authorisation means—

(a) a standard health benefit claim for the NHP; or

(b) a health benefit claim set out in the NHP's market authorisation (a **custom health benefit claim**).

(3) A **permitted health benefit claim** for an NHP that does not have a market authorisation means—

(a) a standard health benefit claim for the NHP; or

(b) in the case of a rongoā product, a claim that the product is beneficial for a particular purpose if there is evidence of its use for that purpose by rongoā practitioners in the provision of rongoā services or activities.

(4) However, subsection (3)(b) does not apply to a claim about a product that the regulations say cannot be made about that product.

Substantiation of health benefit claim

(5) If a provision of this Act requires a health benefit claim about an NHP to be substantiated, the claim must be substantiated—

(a) by scientific evidence, evidence of traditional use, or both; and

(b) in accordance with any requirements in the rules.

(6) Information about the traditional use of a product or ingredient that is in a pharmacopeia listed in the regulations is sufficient evidence of that use unless there is evidence to the contrary.

63 Standard health benefit claims

(1) The rules may set out health benefit claims that may be made about NHPs.

(2) A **standard health benefit claim** for an NHP is one that the rules say may be made about the NHP.

(3) The rules may include health benefit claims that can only be made about an NHP if—

(a) the Regulator is satisfied that the NHP meets criteria that are specified in the rules; and

(b) the claim is identified in the NHP's market authorisation as one that can be made about the NHP.

(4) Subsection (3) does not limit how the rules may identify which claims may be made about which NHPs.

(5) The Regulator must not make rules about a health benefit claim for an NHP unless satisfied on reasonable grounds that the claim is substantiated in accordance with section 62(5) and (6).

Amendment of rules

(6) A person may apply to the Regulator to have the rules amended to add or amend a standard health benefit claim.

(7) An application must include evidence to substantiate the amended or additional claim.

(8) Subsections (6) and (7) do not limit the Regulator's ability to amend the rules on their own initiative.

Guidance note

The procedural and administrative requirements in sections 379 to 386 apply to an application under this section.

Decisions on applications made under this section are reviewable under subpart 6 of Part 9.

64 Product standards

(1) The rules may set standards (**product standards**) for therapeutic products.

(2) The product standards may (without limitation) relate to any of the following:

(a) the products themselves, including,—

(i) if they are medicines, anything relating to their safety, quality, and efficacy:

(ii) if they are medical devices, anything relating to their safety, quality, and performance:

(iii) if they are NHPs,—

(A) anything relating to their safety and quality:

(B) maximum concentrations of NHP ingredients:

(C) other matters relating to their composition:

(b) the responsible manufacturer's quality management systems, including conformity assessment procedures:

(c) any other aspect of the products' manufacture:

(d) identification and labelling of the products:

(e) packages for, and the packaging of, the products:

(f) product information and consumer information for the products.

(3) However, a provision of a product standard does not apply to a therapeutic product with a market authorisation—

(a) if the authorisation says it does not apply; or

(b) to the extent that meeting the standard would cause the product to not conform to the market authorisation.

65 Senior manager

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

(a) person A is a director of person B; or

(b) person A is the chief executive (by whatever name called) of person B; or

(c) if person B is a Crown entity, person A is a member of the board of the Crown entity; or

(d) 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 financial officer); or

(e) 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.

(2) However, if a person holds an advisory position or is a member of a board or other entity that has an advisory role, the person is not a senior manager by reason only of holding that position.

(3) In this section,—

Crown entity has the same meaning as in section 10 of the Crown Entities Act 2004

director has the same meaning as in section 6 of the Financial Markets Conduct Act 2013

member and **board**, in relation to a Crown entity, have the same meanings as in section 10 of the Crown Entities Act 2004.

66 Special-case requirement

(1) This section applies for the purposes of a provision of this Act that allows a health practitioner or veterinarian to carry on a controlled activity with a medicine or medical device that does not have a standard authorisation or provisional authorisation in relation to a patient if the special-case requirement is met.

(2) The **special-case requirement** is met if the health practitioner or veterinarian, exercising their professional judgement, is satisfied that—

(a) there is no medicine or medical device with a standard authorisation or provisional authorisation that—

(i) is suitable to meet the clinical needs of the patient (whether as an authorised indication or an off-label use); and

(ii) is immediately available or could be obtained within a reasonable period; and

(iii) is reasonably affordable to the patient or their whānau; and

(b) it is appropriate to carry on the activity with the medicine or device that does not have a standard authorisation or provisional authorisation.

(3) For the purposes of subsection (2)(a)(iii) and (b), the health practitioner or veterinarian must have regard to any criteria, and comply with any requirements, in the regulations about how affordability and appropriateness are to be assessed.

67 Work

(1) To **work** in a business or undertaking or for a person means to carry out work in any capacity in the business or undertaking 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 undertaking or for the person:

(e) an outworker (including a homeworker (as defined in section 5 of the Employment Relations Act 2000)):

(f) an apprentice, a trainee, or a student undertaking practical training:

(g) a person gaining work experience or undertaking a work trial:

(h) a constable (as defined in section 4 of the Policing Act 2008):

(i) a member of the Armed Forces:

(j) a volunteer worker.

(2) Without limiting subsection (1), a person works for a health practitioner or veterinarian if they work in the same business or undertaking as the health practitioner or veterinarian and are not a health practitioner or veterinarian.

(3) A volunteer is a volunteer worker only to the extent that they are carrying out activities that are an integral part of the controlled activities or supply chain activities carried out by the business or undertaking or person in or for whom the volunteer is working.

Part 3
Dealing with therapeutic products

Subpart 1—Market authorisation requirements

Guidance note

Not complying with a provision of this subpart may be an offence, a civil penalty contravention, or an infringement offence (*see* subparts 2 to 5 of Part 8).

68 Market authorisation required to import, supply, or export

(1) A person must not import or supply a medicine or medical device unless—

(a) the medicine or medical device has a standard authorisation or provisional authorisation; or

(b) a licence, permit, or provision of subpart 3 allows the person to do so.

(2) A person must not export a medicine or medical device unless—

(a) the medicine or medical device has a standard authorisation, provisional authorisation, or export authorisation; or

(b) a licence, permit, or provision of subpart 3 allows the person to do so.

(3) A person must not, in the course of a business or undertaking, import or supply an NHP unless—

(a) the NHP has a standard authorisation; or

(b) a licence, permit, or provision of subpart 3 allows the person to do so; or

(c) the NHP is a low-concentration NHP.

(4) A person must not, in the course of a business or undertaking, export an NHP unless—

(a) the NHP has a standard authorisation or an export authorisation; or

(b) a licence, permit, or provision of subpart 3 allows the person to do so; or

(c) the NHP is a low-concentration NHP.

Guidance note

A medicine or medical device with a market authorisation is authorised only for its authorised indications (*see* section 131).

Other provisions of this Act (such as section 69 and subpart 2 (including section 70)) impose further restrictions on who can import, supply, or export medicines, medical devices, and NHPs and how they must do so. The person must comply with those provisions as well as this section.

69 Sponsor's consent required to import product with standard authorisation or provisional authorisation

A person must not, in the course of a business or undertaking, import a medicine, a medical device, or an NHP with a standard authorisation or provisional authorisation unless—

(a) they are its sponsor; or

(b) they import it with the written consent of its sponsor; or

(c) a licence, permit, or provision of subpart 3 allows them to import it without the sponsor's consent.

Subpart 2—Controlled activities and supply chain activities

Guidance note

Not complying with a provision of this subpart may be an offence, a civil penalty contravention, or an infringement offence (*see* subparts 2 to 5 of Part 8).

70 Controlled activity prohibited unless allowed by licence, permit, or subpart 3

(1) A person must not carry on a controlled activity unless a licence, permit, or provision of subpart 3 allows them to do so.

(2) Each of the following is a **controlled activity**:

(a) in relation to medicines,—

(i) manufacturing (which includes compounding):

(ii) wholesale supply of a prescription medicine, pharmacist medicine, or pharmacy medicine:

(iii) non-wholesale supply of a prescription medicine:

(iv) non-wholesale supply of a pharmacist medicine or pharmacy medicine in the course of a business or undertaking:

(v) exporting:

(vi) dispensing:

(vii) prescribing:

(viii) administering a prescription medicine:

(ix) possessing a prescription medicine:

(x) issuing a standing order:

(xi) conducting a clinical trial:

(b) in relation to medical devices,—

(i) manufacturing:

(ii) wholesale supply:

(iii) non-wholesale supply of a supply-restricted device contrary to the restrictions referred to in section 27(1):

(iv) exporting:

(v) using a use-restricted device on a person or an animal contrary to the restrictions referred to in section 27(2):

(vi) conducting a clinical trial:

(c) in relation to APIs,—

(i) manufacturing:

(ii) wholesale supply of a prescription API:

(iii) exporting:

(iv) possessing a prescription API:

(d) in relation to NHPs, in the case of a person acting in the course of a business or undertaking,—

(i) manufacturing:

(ii) exporting:

(iii) importing a low-concentration NHP:

(e) carrying on a pharmacy business.

71 Non-wholesale supply of prescription medicine: prescription required

A person must not supply by non-wholesale supply a prescription medicine unless—

(a) they supply it in accordance with a complying prescription to the patient for whom it is prescribed; or

(b) they are a recognised prescriber for the medicine; or

(c) a licence, permit, or provision of subpart 3 allows them to supply it without a complying prescription.

72 Administering NHP by injection or parenteral infusion

A person must not administer an NHP to a person by injection or parenteral infusion.

73 Person in supply chain must comply with rules

(1) A person in the supply chain must comply with any requirements in the rules about any of the following:

(a) how supply chain activities are carried on (*see* subsection (2)):

(b) product information and consumer information:

(c) identification and labelling:

(d) packages and packing:

(e) health benefit claims about NHPs:

(f) storage, handling, security, transport, and disposal:

(g) exporting:

(h) tracing and recall (*see* subsection (3)):

(i) post-market surveillance and response:

(j) quality assurance:

(k) record keeping and auditing:

(l) giving information to the Regulator:

(m) giving information and other assistance to sponsors to enable them to comply with their obligations under this Act:

(n) in relation to standing orders, ongoing monitoring and reviewing by the issuer of a standing order (*see* subsection (4)).

(2) Rules made for the purposes of subsection (1)(a) may (without limitation) relate to any of the following:

(a) when, where, and how an activity is carried on, including—

(i) the circumstances in which the activity may be carried on:

(ii) the persons who may be involved in carrying on the activity:

(b) carrying on the activity with therapeutic products that are—

(i) damaged:

(ii) past their expiry date:

(c) the premises, equipment, and materials used in carrying on the activity:

(d) the processes, practices, methods, and procedures used in carrying on the activity:

(e) quality control and assurance requirements relating to the activity:

(3) Rules made for the purposes of subsection (1)(h) 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.

(4) Rules made for the purposes of subsection (1)(n) may (without limitation) relate to monitoring and reviewing any of the following:

(a) the need for a standing order:

(b) the appropriateness of the terms of the order:

(c) the conduct of persons exercising authority under the order.

(5) Rules made for this section cannot impose qualification, training, and competency requirements for individuals involved in carrying on supply chain activities (*see instead* section 74).

74 Person in supply chain must comply with qualification, training, and competency requirements

(1) A person in the supply chain,—

(a) if they are an individual, must not carry on a qualifying activity unless they meet the qualification, training, and competency requirements for the activity; and

(b) must ensure that no person working for them carries on a qualifying activity unless that person meets the qualification, training, and competency requirements for the activity.

(2) An activity that is, or is part of, a supply chain activity is a **qualifying activity** if the regulations say it may be carried on only by a person who meets qualification, training, and competency requirements in the regulations.

75 Prohibited products

(1) A person must not import, manufacture, supply, export, prescribe, administer, use on a person or an animal, or acquire for the purposes of carrying on a supply chain activity a prohibited product unless a permit expressly allows them to do so.

(2) This section overrides any other provision of this Act.

Guidance note

If a product becomes a prohibited product, the Regulator may issue a prohibited product order requiring a person who has any of the product to destroy it or give it to the Regulator, who may destroy it (*see* sections 227 and 247).

76 Vending machines for medicine only if expressly allowed

A person who is otherwise allowed by a licence, permit, or provision of subpart 3 to supply a medicine is not allowed to supply it using a vending machine unless the licence, permit, or provision expressly says that they may do so.

Subpart 3—When activities are allowed

Guidance note

A person who is allowed by this subpart to do something for the purposes of a provision of subpart 1 or 2 is still required to comply with all the other provisions of those subparts that apply to them (including complying with rules made for the purposes of section 73).

Pharmacists

77 Pharmacist: compounding

(1) This section applies for the purposes of section 70(1) and (2)(a)(i).

(2) A pharmacist is allowed to compound a medicine that requires compounding if—

(a) they comply with the pharmacy licence requirements; and

(b) one of the following applies:

(i) they have received a complying prescription for the medicine and compound the medicine in accordance with the prescription:

(ii) they believe on reasonable grounds that—

(A) they might receive a complying prescription for the medicine; and

(B) it is reasonable to produce the medicine in anticipation of receiving the prescription:

(iii) they compound it in circumstances set out in the rules as circumstances in which the medicine may be compounded.

(c) the medicine meets the product standards that apply to it.

(3) A pharmacist may, in reliance on subsection (2)(b)(ii), compound a quantity of the medicine sufficient to meet the number of prescriptions that it is reasonable to think they might receive.

Guidance note

If a medicine is compounded in anticipation of receiving a prescription, the pharmacist cannot dispense it or supply it to the patient until they have received a complying prescription (see sections 78(3)(c)(i) and 79(3)(d)(i)).

78 Pharmacist: dispensing

(1) This section applies for the purposes of section 70(1) and (2)(a)(vi).

(2) A pharmacist is allowed to dispense a medicine (whether or not it has a market authorisation or is supplied for an authorised indication or off-label use).

(3) However, they are allowed to do so only if—

(a) they comply with the pharmacy licence requirements; and

(b) in the case of a prescription medicine, they dispense it in accordance with a complying prescription; and

(c) in the case of a medicine that does not have a standard authorisation or provisional authorisation for any indications,—

(i) they dispense it in accordance with a complying prescription; and

(ii) if it is a medicine that requires compounding, it is lawfully compounded.

79 Pharmacist: non-wholesale supply

(1) This section applies for the purposes of sections 68 and 70(1) and (2)(a)(iii) and (iv).

(2) A pharmacist is allowed to supply a medicine or medical device by non-wholesale supply (whether or not it has a market authorisation or is supplied for an authorised indication or off-label use).

(3) However, they are allowed to do so only if—

(a) they comply with the pharmacy licence requirements; and

(b) in the case of a prescription medicine, they comply with section 71; and

(c) in the case of a pharmacist medicine, they supply it—

(i) in accordance with a complying prescription; or

(ii) after they have determined that it is appropriate for the patient; and

(d) in the case of a medicine that does not have a standard authorisation or provisional authorisation for any indications,—

(i) they supply it in accordance with a complying prescription; and

(ii) in the case of a medicine that requires compounding, it is lawfully compounded; and

(e) in the case of a medical device that does not have a standard authorisation or provisional authorisation for any indications, they supply it—

(i) to a specific patient; and

(ii) at the request of a health practitioner or veterinarian who is allowed by section 84 or 94 to supply it to the patient.

(4) They are allowed to do so without complying with subsection (3) if it is a general-sale medicine or medical device that has a standard authorisation or provisional authorisation (whether supplied for an authorised indication or an off-label use).

(5) They are allowed to do so without complying with subsection (3)(a) if it is a pharmacy medicine and is supplied in the course of a business or undertaking that is not a pharmacy business (and for which there is, therefore, not a pharmacy licence).

80 Pharmacist: exporting

(1) This section applies for the purposes of sections 68 and 70(1) and (2)(a)(v) and (b)(iv).

(2) A pharmacist is allowed to export a medicine or medical device if—

(a) the recipient is ordinarily resident in New Zealand; and

(b) the pharmacist would be allowed by section 79 to supply it by non-wholesale supply to the person if the person were in New Zealand.

81 Pharmacist: importing

(1) This section applies for the purposes of section 68.

(2) A pharmacist is allowed to import a medicine or medical device (whether or not it has a market authorisation or is supplied for an authorised indication or off-label use).

(3) However, they are allowed to do so only if—

(a) they comply with the pharmacy licence requirements; and

(b) they import it for the purposes of supplying it to a specific patient to whom they are allowed to supply it under section 79.

82 Pharmacist: wholesale supply to transfer stock

(1) This section applies for the purposes of sections 68 and 70(1) and (2)(a)(i) and (ii) and (b)(i) and (ii).

(2) A pharmacist is allowed to supply by wholesale supply a medicine or medical device if—

(a) they have possession of it for the purpose of carrying on a different controlled activity; and

(b) the recipient is a pharmacist, health practitioner, or veterinarian; and

(c) the pharmacist complies with the pharmacy licence requirements; and

(d) any requirements in the rules about that supply are complied with.

Manufacturing

(3) The pharmacist is allowed to take a post-production step in the manufacture of the medicine or device (such as packing or labelling it) if—

(a) taking the step is reasonably necessary to enable that supply; and

(b) the pharmacist complies with the pharmacy licence requirements; and

(c) any requirements in the rules about taking that step are complied with.

Qualified pharmacy workers

83 Qualified pharmacy worker

(1) This section applies for the purposes of sections 68 and 70.

(2) A pharmacy worker working in a pharmacy business is allowed to carry on an activity that sections 77 to 81 allow a pharmacist in the business to carry on if the worker—

(a) is qualified to carry on the activity; and

(b) carries on the activity in a way that the pharmacist is allowed to do; and

(c) carries on the activity under the supervision of a pharmacist provided in accordance with the rules.

(3) Rules made for the purposes of subsection (2)(c) may (without limitation) relate to either of the following:

(a) the level of supervision required for an activity:

(b) the methods by which that level of supervision must or may be provided.

(4) Any limitations on how the supervising pharmacist is allowed to carry on the activity also apply to the pharmacy worker.

(5) To avoid doubt, section 79(3)(c)(ii), as applied by subsection (2) of this section, requires the appropriateness of the medicine for the patient to be determined by a pharmacist, not by the pharmacy worker.

Health practitioners

84 Health practitioner: non-wholesale supply

(1) This section applies for the purposes of sections 68 and 70(1) and (2)(a)(iii) and (iv).

(2) A health practitioner is allowed to supply a medicine or medical device by non-wholesale supply (whether or not it has a market authorisation or is supplied for an authorised indication or off-label use).

(3) However, they are allowed to do so only if,—

(a) in the case of a prescription medicine or pharmacist medicine, they are a health practitioner prescriber for the medicine; and

(b) in the case of a pharmacy medicine or a medical device, it is relevant to a health service that forms part of the practitioner's scope of practice; and

(c) they supply it—

(i) to a patient of the practitioner; or

(ii) to a patient of, and at the request of, another health practitioner who is allowed by this section to supply the medicine or device to the patient; and

(d) in the case of a medicine that requires compounding, it is lawfully compounded; and

(e) in the case of a medicine or device that does not have a standard authorisation or provisional authorisation for any indications, the special-case requirement is complied with.

(4) They are allowed to do so without complying with subsection (3) if it is a general-sale medicine or medical device that has a standard authorisation or provisional authorisation (whether supplied for an authorised indication or an off-label use).

85 Health practitioner: prescribing

(1) This section applies for the purposes of sections 68 and 70(1) and (2)(a)(vii).

(2) A health practitioner is allowed to prescribe a medicine (whether or not it has a market authorisation or is supplied for an authorised indication or off-label use).

(3) However, they are allowed to do so only if—

(a) they are a health practitioner prescriber for that medicine; and

(b) they prescribe it—

(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) in the case of a medicine that does not have a standard authorisation or provisional authorisation for any indications, the special-case requirement is complied with; and

(e) any requirements about complying prescriptions in rules made for the purposes of section 54 are complied with.

Guidance note

A prescription is required for non-wholesale supply of a prescription medicine (*see* section 71). A prescription can be issued for other medicines even though it is not required.

86 Health practitioner: administering

(1) This section applies for the purposes of sections 68 and 70(1) and (2)(a)(viii).

(2) A health practitioner is allowed to administer a prescription medicine (whether or not it has a market authorisation or is supplied for an authorised indication or off-label use).

(3) However, they are allowed to do so only if—

(a) they are a health practitioner prescriber for that medicine; and

(b) they administer it—

(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; and

(c) in the case of a medicine that requires compounding, it is lawfully compounded; and

(d) in the case of a medicine that does not have a standard authorisation or provisional authorisation for any indications, the special-case requirement is complied with.

Guidance note

Administering a medicine is a controlled activity for prescription medicines only.

87 Health practitioner: dispensing

(1) This section applies for the purposes of section 70(1) and (2)(a)(vi).

(2) A health practitioner is allowed to dispense a medicine (whether or not it has a market authorisation or is supplied for an authorised indication or off-label use).

(3) However, they are allowed to do so only if—

(a) they are a health practitioner prescriber for that medicine; and

(b) they dispense it—

(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) in the case of a medicine that requires compounding, it is lawfully compounded; and

(e) in the case of a medicine that does not have a standard authorisation or provisional authorisation for any indications, the special-case requirement is complied with.

88 Health practitioner: exporting

(1) This section applies for the purposes of sections 68 and 70(1) and (2)(a)(v) and (b)(iv).

(2) A health practitioner is allowed to export a medicine or medical device if they export it to a patient—

(a) to whom they would be allowed to supply it if the patient were in New Zealand; and

(b) who is ordinarily resident in New Zealand.

89 Health practitioner: importing

(1) This section applies for the purposes of section 68.

(2) A health practitioner is allowed to import a medicine that does not have a standard authorisation or provisional authorisation for any indication if—

(a) they import it for the purpose of supplying or administering it to a patient to whom they are allowed to supply or administer it; and

(b) the special-case requirement is complied with; and

(c) it is not a medicine that requires compounding.

(3) A health practitioner is allowed to import a medical device that does not have a standard authorisation or provisional authorisation for any indication if—

(a) they import it for the purpose of supplying it to a patient to whom they are allowed to supply it, or on whom they are allowed to use it; and

(b) the special-case requirement is complied with.

90 Health practitioner: wholesale supply to transfer stock

(1) This section applies for the purposes of sections 68 and 70(1) and (2)(a)(i) and (ii) and (b)(i) and (ii).

(2) A health practitioner is allowed to supply by wholesale supply a medicine or medical device if—

(a) they have possession of it for the purpose of carrying on a different controlled activity; and

(b) the recipient is a pharmacist, health practitioner, or veterinarian; and

(c) any requirements in the rules about that supply are complied with.

(3) The health practitioner is allowed to take a post-production step in the manufacture of the medicine or device (such as packing or labelling it) if—

(a) taking the step is reasonably necessary to enable that supply; and

(b) any requirements in the rules about taking that step are complied with.

91 Health practitioner: producing medical device using device production system

(1) This section applies for the purposes of section 46(1).

(2) A health practitioner is allowed to produce a medical device using a device production system if—

(a) the device is relevant to a health service that forms part of the practitioner's scope of practice; and

(b) they produce it—

(i) for a patient of the health practitioner; or

(ii) for a patient of, and at the request of, another health practitioner to whom paragraph (a) applies; and

(c) any requirements in the rules about producing the device are complied with.

92 Health practitioner: standing orders

(1) This section applies for the purposes of section 70(1) and (2)(a)(x).

(2) A health practitioner is allowed to issue a standing order for 1 or more medicines with a standard authorisation or provisional authorisation.

(3) However, the health practitioner is allowed to do so only if—

(a) they are a health practitioner prescriber for every medicine specified in the standing order; and

(b) their scope of practice includes issuing standing orders for those medicines; and

(c) every person to whom the order applies 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 allows a person to do is something that the practitioner is allowed to do; and

(e) any requirements about standing orders in rules made for the purposes of section 55 are complied with.

Guidance note

The controlled activities that may be included in a standing order are set out in section 55.

Health practitioners' staff

93 Health practitioner's staff: non-wholesale supply

(1) This section applies for the purposes of sections 68 and 70(1) and (2)(a)(iv).

(2) A person who works for a health practitioner is allowed to supply by non-wholesale supply a pharmacy medicine with a standard authorisation or provisional authorisation.

(3) However, they are allowed to do so only if—

(a) section 84 allows the health practitioner to supply it; and

(b) it is supplied for an authorised indication; and

(c) the worker supplies it—

(i) to a patient of the health practitioner; and

(ii) under the general supervision of the health practitioner.

(4) Any limitations on how the health practitioner is allowed to supply the medicine also apply to the worker.

(5) The requirement in subsection (3)(c)(ii) for general supervision—

(a) does not require the health practitioner to be physically present when the worker carries on the activity; but

(b) requires the health practitioner to be easily contactable by the worker in a way that enables the health practitioner to answer any questions the worker may have about carrying on the activity.

Veterinarians

94 Veterinarian: non-wholesale supply

(1) This section applies for the purposes of sections 68 and 70(1) and (2)(a)(iii) and (iv).

(2) A veterinarian is allowed to supply a medicine or medical device by non-wholesale supply (whether or not it has a market authorisation).

(3) However, they are allowed to do so only if—

(a) they supply it—

(i) to a patient of the veterinarian; or

(ii) to a patient of, and at the request of, another veterinarian; and

(b) in the case of a medicine that requires compounding, it is lawfully compounded; and

(c) in the case of a medicine or medical device that does not have a standard authorisation or provisional authorisation for any indications, the special-case requirement is complied with.

(4) They are allowed to do so without complying with subsection (3) if it is a general-sale medicine or medical device that has a standard authorisation or provisional authorisation.

95 Veterinarian: prescribing

(1) This section applies for the purposes of sections 68 and 70(1) and (2)(a)(vii).

(2) A veterinarian is allowed to prescribe a medicine (whether or not it has a market authorisation).

(3) However, they are allowed to do so only if—

(a) they prescribe it—

(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) in the case of a medicine that does not have a standard authorisation or provisional authorisation for any indications, the special-case requirement is complied with; and

(d) any requirements about complying prescriptions in rules made for the purposes of section 54 are complied with.

Guidance note

A prescription is required for non-wholesale supply of a prescription medicine (*see* section 71). A prescription can be issued for other medicines even though it is not required.

96 Veterinarian: administering

(1) This section applies for the purposes of sections 68 and 70(1) and (2)(a)(viii).

(2) A veterinarian is allowed to administer a prescription medicine (whether or not it has a market authorisation).

(3) However, they are allowed to do so only if—

(a) they administer it—

(i) to a patient of the veterinarian; or

(ii) to a patient of, and at the request of, another veterinarian; and

(b) in the case of a medicine that requires compounding, it is lawfully compounded; and

(c) in the case of a medicine that does not have a standard authorisation or provisional authorisation for any indications, the special-case requirement is complied with.

97 Veterinarian: dispensing

(1) This section applies for the purposes of section 70(1) and (2)(a)(vi).

(2) A veterinarian is allowed to dispense a medicine (whether or not it has a market authorisation).

(3) However, they are allowed to do so only if—

(a) they dispense it—

(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) in the case of a medicine that requires compounding, it is lawfully compounded; and

(d) in the case of a medicine that does not have a standard authorisation or provisional authorisation for any indications, the special-case requirement is complied with.

98 Veterinarian: exporting

(1) This section applies for the purposes of sections 68 and 70(1) and (2)(a)(v) and (b)(iv).

(2) A veterinarian is allowed to export a medicine or medical device if they export it to a patient—

(a) to whom they would be allowed to supply it if the patient were in New Zealand; and

(b) who is ordinarily resident in New Zealand.

99 Veterinarian: importing

(1) This section applies for the purposes of section 68.

(2) A veterinarian is allowed to import a medicine that does not have a standard authorisation or provisional authorisation for any indication if—

(a) they import it for the purpose of supplying or administering it to a patient to whom they are allowed to supply or administer it; and

(b) the special-case requirement is complied with; and

(c) it is not a medicine that requires compounding.

(3) A veterinarian is allowed to import a medical device that does not have a standard authorisation or provisional authorisation for any indication if—

(a) they import it for the purpose of supplying it to a patient to whom they are allowed to supply it, or on whom they are allowed to use it; and

(b) the special-case requirement is complied with.

100 Veterinarian: wholesale supply to transfer stock

(1) This section applies for the purposes of sections 68 and 70(1) and (2)(a)(i) and (ii) and (b)(i) and (ii).

(2) A veterinarian is allowed to supply by wholesale supply a medicine or medical device if—

(a) they have possession of it for the purpose of carrying on a different controlled activity; and

(b) the recipient is a pharmacist, health practitioner, or veterinarian; and

(c) any requirements in the rules about that supply are complied with.

(3) The veterinarian is allowed to take a post-production step in the manufacture of the medicine or device (such as packing or labelling it) if—

(a) taking the step is reasonably necessary to enable that supply; and

(b) any requirements in the rules about taking that step are complied with.

101 Veterinarian: producing medical device using device production system

(1) This section applies for the purposes of section 46(1).

(2) A veterinarian is allowed to produce a medical device using a device production system if—

(a) they produce it—

(i) for a patient of the veterinarian; or

(ii) for a patient of, and at the request of, another veterinarian; and

(b) any requirements in the rules about producing the device are complied with.

Veterinarians' staff

102 Veterinarian's staff

(1) This section applies for the purposes of sections 68 and 70.

(2) A person who works for a veterinarian is allowed to supply by non-wholesale supply a pharmacy medicine with a standard authorisation or provisional authorisation if—

(a) section 94 allows the veterinarian to supply it; and

(b) the worker supplies it—

(i) to a patient of the veterinarian; and

(ii) under the general supervision of the veterinarian.

(3) A person who works for a veterinarian is allowed to carry on any other controlled activity referred to in section 94 (if subsection (2) does not apply), or section 96, 97, or 101 if—

(a) those sections allow the veterinarian to carry on the activity; and

(b) the worker carries on the activity—

(i) in a way that the veterinarian is allowed to do; and

(ii) at the request of, and under the direct supervision of, the veterinarian.

(4) Any limitations on how the veterinarian is allowed to carry on the activity also apply to the worker.

(5) The requirement in subsection (2)(b)(ii) for general supervision—

(a) does not require the veterinarian to be physically present when the worker carries on the activity; but

(b) requires the veterinarian to be easily contactable by the worker in a way that enables the veterinarian to answer any questions the worker may have about carrying on the activity.

Person acting under standing order

103 Person acting under standing order

(1) This section applies for the purposes of sections 70(1) and (2)(a)(iii), (iv), and (viii) and 71.

(2) A person is allowed to carry on an activity that a standing order allows them to carry on.

Guidance note

The controlled activities that may be included in a standing order are set out in section 55.

Downstream activities

104 Downstream supply or administration of medicine to patient

(1) This section applies for the purposes of sections 68, 70(1) and (2)(a)(iii), (iv), and (viii), and 71.

(2) If a medicine is lawfully supplied by non-wholesale supply to a person (**person A**) who is not the patient for whom the medicine is intended,—

(a) person A is allowed to supply it to the patient and, in the case of a prescription medicine, to do so without a complying prescription; and

(b) in the case of a prescription medicine, person A is allowed to administer it to the patient in accordance with the directions of the recognised prescriber who supplied or prescribed it.

(3) If a medical device that does not have a standard authorisation or provisional authorisation is lawfully supplied by non-wholesale supply to a person (**person B**) who is not the patient for whom the device is intended, person B is allowed to supply it to the patient.

105 Possession of prescription medicine or prescription API

(1) This section applies for the purposes of section 70(1) and (2)(a)(ix) and (c)(iv).

(2) A person is allowed to possess a prescription medicine if—

(a) it was lawfully supplied to them by non-wholesale supply; or

(b) they are allowed by a licence, permit, or provision of this Act to carry on a controlled activity with the medicine and they have possession of it incidental to carrying on that activity.

(3) A person is allowed to possess a prescription API if—

(a) it was lawfully supplied to them; or

(b) they are allowed by a licence, permit, or provision of this Act to carry on a controlled activity with the API or with a medicine that contains the API and their possession of the API is incidental to carrying on that activity.

Personal use imports

106 Patient or carer importing medicine for personal use

(1) This section—

(a) applies for the purposes of sections 68 and 69; but

(b) does not apply to a medicine that the rules say cannot be imported under this section.

(2) An individual (**person A**) is allowed to import a medicine (whether or not it has a standard authorisation or provisional authorisation) if they comply with the personal use import conditions.

(3) If the medicine has a standard authorisation or provisional authorisation, they are allowed to do so without the sponsor's consent.

(4) 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) a specific person or animal for whom person A is a carer; and

(c) the medicine is imported with the intention of it being used by the patient in New Zealand; and

(d) in importing the medicine, person A is not acting in the course of a business or undertaking; and

(e) either—

(i) the luggage conditions in subsection (5) are complied with; or

(ii) the delivery conditions in subsection (6) are complied with; and

(f) any other requirements in the rules about importing medicines for personal use are complied with.

(5) 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 any one time does not exceed,—

(i) if the medicine was prescribed by a recognised prescriber or an overseas health professional or veterinarian, the amount prescribed; or

(ii) otherwise, 3 months' standard supply.

(6) The **delivery conditions** are that—

(a) in the case of a prescription medicine, the medicine has been lawfully prescribed in New Zealand for the patient by or for whom it is imported; and

(b) the amount of the medicine imported by person A at any 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.

(7) If a medicine obtained overseas is imported in reliance on this section, sections 104 and 105 apply as if the medicine had been supplied in New Zealand.

(8) Section 104(2)(b), as applied by subsection (7) of this section, is taken to refer to the directions of the overseas health professional or veterinarian who supplied or prescribed the medicine (or if it was not supplied or prescribed by a health professional or veterinarian, to the responsible manufacturer's instructions).

(9) 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 as the patient would require for that number of months, calculated on the basis of the recommended daily dose specified by the medicine's responsible manufacturer.

107 Patient or carer importing medical device for personal use

(1) This section—

(a) applies for the purposes of sections 68 and 69; but

(b) does not apply to a medical device that the rules say is one that cannot be imported under this section.

(2) An individual (**person A**) is allowed to import a medical device that does not have a standard authorisation or provisional authorisation if—

(a) person A acquired the device lawfully; and

(b) 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

(c) the device is imported with the intention of it being used on the patient in New Zealand; and

(d) in importing the device, person A is not acting in the course of a business or undertaking; and

(e) any other requirements in the rules about importing devices for personal use are complied with.

Personal export

108 Personal export of medicine or medical device

(1) This section—

(a) applies for the purposes of sections 68 and 70(1) and (2)(a)(v) and (b)(iv); but

(b) does not apply to a medicine or medical device that the rules say is one that cannot be exported under this section.

(2) An individual (**person A**) is allowed to export a medicine or medical device (whether or not it has a market authorisation) if they comply with the personal export conditions.

(3) The **personal export conditions** are that—

(a) person A acquired the medicine or medical device lawfully; and

(b) in exporting the medicine or device, person A is not acting in the course of a business or undertaking; and

(c) in the case of a medicine, the amount exported by person A at any one time does not exceed,—

(i) if the medicine was prescribed by a recognised prescriber or an overseas health professional or veterinarian, the amount prescribed; or

(ii) otherwise, 6 months' standard supply; and

(d) any other requirements in the rules about exporting medicines or medical devices are complied with.

(4) A reference to 6 months' **standard supply** of a medicine means the amount of the medicine that a notional average patient with the same condition as the patient would require for 6 months, calculated on the basis of the recommended daily dose specified by the medicine's responsible manufacturer.

Personalised medical devices

109 Manufacture of custom-made devices

(1) This section applies for the purposes of sections 68 and 70(1) and (2)(b)(i), (ii), and (iv).

(2) A person is allowed to manufacture a custom-made device if—

(a) they are in a class of persons that the regulations say are allowed to manufacture the device; and

(b) they manufacture it at the request of a health practitioner or veterinarian for a specific patient of that practitioner or veterinarian; and

(c) the device meets the product standards that apply to it; and

(d) any requirements in the rules about that manufacture are complied with.

(3) The person is allowed to supply the device to the health practitioner or veterinarian who requested it or to the patient.

(4) The person is allowed to export the device to the patient if the patient is ordinarily resident in New Zealand.

110 Producing medical device using device production system

(1) This section applies for the purposes of sections 46(1)(a) and 70(1) and (2)(b)(i), (ii), and (iv).

(2) A person is allowed to use a device production system to produce a patient-matched device if—

(a) they are in a class of persons that the regulations say are allowed to use the system to produce the device; and

(b) they produce the device—

(i) at the request of a health practitioner or veterinarian who would be allowed to produce it under section 91 or 101; and

(ii) for a specific patient of that practitioner or veterinarian; and

(c) any requirements in the rules about using the system to produce the device are complied with.

(3) The person is allowed to supply the device to the health practitioner or veterinarian who requested it or to the patient.

(4) The person is allowed to export the device to the patient if the patient is ordinarily resident in New Zealand.

Sponsors of medicines and medical devices

111 Export by sponsor of medicine or medical device

(1) This section applies for the purposes of section 70(1) and (2)(a)(v) and (b)(iv).

(2) The sponsor of a medicine or medical device with a market authorisation is allowed to export it.

NHPs

112 Rongoā

(1) This section applies for the purposes of sections 68 and 70(1) and (2)(d)(i) and (ii).

(2) Section 70(1) and (2)(d)(i) does not prevent a rongoā practitioner, or an associate of the practitioner, from manufacturing a rongoā product that does not have a market authorisation.

(3) Sections 68 and 70(1) and (2)(d)(ii) do not prevent a rongoā practitioner, or an associate of the practitioner, from supplying a rongoā product that does not have a market authorisation—

(a) to a client of the rongoā practitioner; or

(b) to another rongoā practitioner, or an associate of that other practitioner, for use in a rongoā service or activity provided by that other practitioner; or

(c) at the request of another rongoā practitioner, to a client of that other practitioner.

(4) Sections 73 and 74 do not apply in relation to—

(a) a rongoā product that does not have a market authorisation; or

(b) a rongoā practitioner engaged in providing a rongoā service or activity (unless they are doing so with a rongoā product that has a market authorisation).

113 Manufacture and export by sponsor of NHP

(1) This section applies for the purposes of section 70(1) and (2)(d)(i) and (ii).

(2) The sponsor of an NHP with a market authorisation is allowed to manufacture and export it.

114 Regulations may allow manufacture and in-person supply of NHP without market authorisation

(1) This section applies for the purposes of sections 68 and 70(1) and (2)(d)(i).

(2) A person acting in the course of business is allowed to manufacture an NHP that does not have a market authorisation if—

(a) either—

(i) the NHP ingredients in the NHP are all recognised NHP ingredients; or

(ii) the NHP is a low-concentration NHP; and

(b) the NHP is of a kind that the regulations say is allowed to be manufactured and supplied in reliance on this section; and

(c) the NHP meets any product standards that apply to it; and

(d) in the case of an NHP that is manufactured for the purpose of being exported, it meets any export standards that apply to it; and

(e) the person is in a class of persons that the regulations say are allowed to manufacture and supply the NHP in reliance on this section; and

(f) any requirements in the regulations or rules about manufacturing the NHP are complied with.

(3) The person is allowed to supply the NHP by non-wholesale supply if—

(a) the supply transaction is conducted—

(i) in an in-person interaction between the supplier and the recipient (or, if either of them is not an individual, by an individual acting on their behalf); or

(ii) in a way allowed by the regulations; and

(b) any requirements in the regulations or rules about supplying the NHP are complied with.

(4) A person who manufactures an NHP in reliance on this section must comply with the following sections as if the product had a standard authorisation and the person were its sponsor, unless the regulations provide otherwise:

(a) section 145 (sponsor must have surveillance and response system):

(b) section 146 (sponsor must comply with rules).

(5) This section does not limit the regulations that may be made for the purposes of section 118.

115 Personalised NHPs

(1) This section applies for the purposes of sections 68 and 70(1) and (2)(d)(i) and (ii).

(2) An NHP practitioner is allowed to manufacture an NHP that does not have a standard authorisation or provisional authorisation if—

(a) a person (the **client**) consults the practitioner about the client's health needs; and

(b) the consultation is carried out in accordance with any consultation requirements in the rules; and

(c) the practitioner determines that the NHP is appropriate to address the client's health needs; and

(d) the practitioner manufactures a quantity of the NHP for the client; and

(e) either—

(i) the NHP ingredients in the product are all recognised NHP ingredients; or

(ii) the NHP is a low-concentration NHP; and

(f) the NHP meets the product standards that apply to it; and

(g) any other requirements in the rules about manufacturing the NHP are complied with.

(3) The NHP practitioner is allowed to supply the NHP if—

(a) they supply it to the client by non-wholesale supply; and

(b) any requirements in the rules about that supply are complied with.

(4) The NHP practitioner is allowed to export the NHP to the client if—

(a) the client is ordinarily resident in New Zealand; and

(b) any requirements in the rules about that export are complied with.

(5) In this section, **NHP practitioner** means an individual (regardless of the title or description they use) who—

(a) carries on a business or undertaking of providing personal consultations with clients to identify the clients' health needs and to supply by non-wholesale supply, or to administer, NHPs to address those needs; or

(b) the rules say is an NHP practitioner.

Cessation of market authorisation

116 Stock in supply chain if market authorisation ceases

(1) This section applies for the purposes of subparts 1 and 2.

(2) Subsection (4) applies if—

(a) the market authorisation for a medicine, a medical device, or an NHP (**product A**) ceases to be in force; and

(b) a use of current stock notice is in force for product A.

(3) A **use of current stock notice** is a Regulator's notice identifying specific stock of product A (**current stock**) as stock to which this section applies.

(4) A person is allowed to carry on any activity with product A if—

(a) they would be allowed to do so if product A's market authorisation were still in force; and

(b) the specific product with which they carry on the activity is current stock.

(5) However, subsection (4) does not apply to the sponsor of product A (in their capacity as sponsor or in any other capacity).

(6) If a person is allowed by this section to carry on an activity with product A, this Act applies as if product A's market authorisation were still in force.

(7) Stock identified in a use of current stock notice—

(a) must exist when the notice is made; and

(b) may be identified in any way the Regulator thinks is appropriate.

Example

Company M is the sponsor of product A and imports and wholesales the product. If product A's market authorisation is cancelled but the Regulator issues a use of current stock notice for stock already in the supply chain, health practitioners, retailers, etc, are allowed 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.

117 Stock in supply chain if unauthorised major change

(1) This section applies for the purposes of subparts 1 and 2.

(2) Subsection (4) applies if—

(a) a major change is made to a medicine, a medical device, or an NHP with a market authorisation (the **original product**) and the changed product is released into the supply chain without a market authorisation; and

(b) a use of current stock notice is in force for the changed product.

(3) A **use of current stock notice** is a Regulator's notice identifying specific stock of the changed product (**current stock**) as stock to which this section applies.

(4) A person is allowed to carry on any activity with the changed product if—

(a) they would be allowed to do so if the original product's market authorisation applied to the changed product; and

(b) the specific product with which they carry on the activity is current stock.

(5) However, subsection (4) does not apply to the sponsor of the original product or the changed product (in their capacity as sponsor or in any other capacity).

(6) If a person is allowed by this section to carry on an activity with the changed product, this Act applies as if the original product's market authorisation applied to the changed product.

(7) Stock identified in a use of current stock notice—

(a) must exist when the notice is made; and

(b) may be identified in any way the Regulator thinks is appropriate.

Other classes of persons specified in regulations

118 Regulations may allow controlled activities to be carried on by other persons

(1) This section applies for the purposes of sections 46(1)(a) and 68 to 72.

(2) A person is allowed to carry on a controlled activity or do something that would otherwise contravene any of those sections if—

(a) they are in a class of persons that the regulations say are allowed to carry on the activity or do the thing; and

(b) any requirements in the rules about doing so are complied with.

Emergency arrangements

119 Emergency arrangements

(1) A person is allowed to do something that would otherwise contravene a provision of subpart 1 or 2 if an emergency arrangements notice allows them to do so.

(2) An **emergency arrangements notice** is a notice, made by the chief executive of the Ministry, that allows a person or class of persons to do something that would otherwise contravene a provision of subpart 1 or 2.

(3) However, an emergency arrangements notice cannot allow anyone to do something with a medicine or medical device that does not have a market authorisation for at least 1 authorised indication (although the notice may allow off-label use).

(4) The chief executive may make an emergency arrangements notice if satisfied on reasonable grounds that—

(a) there is a significant risk to the health of persons or animals in New Zealand; and

(b) the nature or magnitude of the risk (or both) is such that, to the extent it relates to therapeutic products, it cannot be adequately managed by the exercise of the Regulator's powers under this Act; and

(c) making the notice is a necessary or desirable way to manage, or assist in the management of, the risk; and

(d) the extent of the notice is not broader than is reasonably necessary for that purpose; and

(e) any other criteria in the regulations are met.

(5) An emergency arrangements notice must set out all of the following:

(a) the provisions in subpart 1 or 2 it relates to:

(b) what the notice allows to be done:

(c) the person or class of persons who are allowed to do it:

(d) the circumstances in which they are allowed to do so:

(e) when the notice takes effect.

(6) An emergency arrangements notice—

(a) may remain in force for as long as the chief executive thinks is necessary or desirable; but

(b) must be revoked by the chief executive as soon as it ceases to be so.

(7) Before making an emergency arrangements notice, the chief executive must—

(a) consult the Regulator and the Minister; and

(b) comply with any requirements in the regulations about making the notice.

(8) An emergency arrangements notice is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

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

This note is not part of the Act.

Part 4
Market authorisations for medicines, medical devices, and NHPs

Subpart 1—Market authorisations

Kinds of market authorisations

120 Kinds of market authorisations

(1) There are 3 kinds of market authorisation as follows:

(a) a **standard authorisation**, which authorises a medicine, a medical device, or an NHP for import, supply, and export on an ongoing basis:

(b) a **provisional authorisation**, which authorises a medicine or medical device for import, supply, and export when the Regulator is not able to determine whether the product meets the criteria for a standard authorisation (for example, because there is insufficient information available) but is satisfied that it is nevertheless appropriate to authorise it on a limited basis:

(c) an **export authorisation**, which authorises a medicine, a medical device, or an NHP for export from New Zealand even though it does not meet the criteria for a standard authorisation that would allow it to be supplied in New Zealand.

(2) An authorisation is issued by the Regulator,—

(a) in the case of a medicine or medical device, under section 121; or

(b) in the case of an NHP, under section 126.

Issuing market authorisations for medicines and medical devices

121 Application and issue of market authorisation for medicine or medical device

(1) A person may apply to the Regulator for a market authorisation for a medicine or medical device.

(2) The Regulator may issue a market authorisation of the kind sought to the person named in the application as the proposed sponsor if—

(a) the Regulator has evaluated the product under section 122; and

(b) the product meets the criteria for a market authorisation of a medicine or medical device in section 123; and

(c) the proposed sponsor meets the criteria for being the sponsor of a medicine or medical device in section 124; and

(d) the Regulator is satisfied that it is appropriate to issue the market authorisation.

(3) However, if the application is for a standard authorisation, the Regulator may instead issue a provisional authorisation for the product.

(4) If a Crown organisation is to be the sponsor, the market authorisation must be issued to the Crown organisation in its own name (and not to the Crown).

(5) If the Regulator is not satisfied of the matters referred to in subsection (2), they must refuse to issue a market authorisation.

Guidance note

The procedural and administrative requirements in sections 379 to 386 apply to an application under this section.

Decisions under this section are reviewable under subpart 6 of Part 9.

122 Evaluation of medicine or medical device

(1) The Regulator must evaluate the product to determine—

(a) whether the following are satisfactorily established:

(i) in the case of a medicine, its safety, quality, and efficacy for its intended authorised indications; or

(ii) in the case of a medical device, its safety, quality, and performance for its intended authorised indications; and

(b) whether the likely benefits of the product outweigh the likely risks associated with it.

(2) The nature and extent of the Regulator's evaluation of the product must be appropriate and proportionate having regard to—

(a) the likely benefits of, and risks associated with, the product; and

(b) the extent of any previous evaluation of the product or a related product; and

(c) any matters set out in the regulations; and

(d) all of the circumstances of the case.

Example

If an application is made for a standard authorisation for a product that currently has a provisional authorisation or that is a result of a major change to a product with a market authorisation, the extent of the evaluation is likely be different from that required for an entirely novel product.

(3) In evaluating the product, the Regulator may (without limitation) have regard to the following:

(a) anything relating to,—

(i) in the case of a medicine, its safety, quality, and efficacy for its intended authorised indications; or

(ii) in the case of a medical device, its safety, quality, and performance for its intended authorised indications:

(b) anything relating to the likely benefits of, and risks associated with, the product:

(c) the kind of market authorisation being sought:

(d) the type of product it is:

(e) in the case of a medicine, the class of medicine it will be:

(f) conditions that might be imposed on the market authorisation under section 136:

(g) conditions set out in the rules, product standards, or export standards that the market authorisation might disapply (*see* section 130):

(h) rules that might be made that would be relevant to whether the market authorisation is issued, for example,—

(i) rules affecting the type of product it is (*see* section 21):

(ii) rules describing the classes of medicines (*see* section 23):

(iii) product standards:

(iv) export standards:

(i) any other matters that the Regulator thinks are relevant.

Guidance note

The Regulator may rely on reports, assessments, or decisions made by, or information received from, a recognised entity (*see* section 354).

123 Criteria for market authorisation of medicine or medical device

(1) A medicine or medical device meets the criteria for a standard authorisation if the Regulator is satisfied on reasonable grounds that all of the following apply:

(a) the following are satisfactorily established:

(i) in the case of a medicine, its safety, quality, and efficacy for its intended authorised indications; or

(ii) in the case of a medical device, its safety, quality, and performance for its intended authorised indications:

(b) the likely benefits of the product outweigh the likely risks associated with it:

(c) the product will meet the product standards that apply to it:

(d) the product is not a prohibited product.

(2) A medicine or medical device (**product A**) meets the criteria for a provisional authorisation if—

(a) the Regulator is not able to determine whether the criterion in subsection (1)(a) is met in relation to product A; and

(b) the Regulator is satisfied that circumstances exist that justify a product being made available in New Zealand despite it not having a standard authorisation; and

(c) the Regulator is satisfied on reasonable grounds that—

(i) if product A is a medicine, its safety, quality, and efficacy for its intended authorised indications; or

(ii) if product A is a medical device, its safety, quality, and performance for its intended authorised indications—

are sufficiently well established that, in the circumstances referred to in paragraph (b), it is reasonable to issue a market authorisation for product A; and

(d) the Regulator is satisfied on reasonable grounds that the criteria in subsection (1)(b) to (d) are met.

(3) A medicine or medical device meets the criteria for an export authorisation if the Regulator is satisfied on reasonable grounds that—

(a) the criteria in subsection (1)(a) to (d) are met; and

(b) the product will meet any export standards that apply to it.

Guidance note

Subsection (2)(a) applies when the Regulator is not able to make a decision about whether the criterion in subsection (1)(a) is met (for example, because full clinical trial data is not yet available). It does not apply if the Regulator is able to make that decision and decides that the criterion is not met.

See also section 136 in relation to the imposition of conditions on a market authorisation.

124 Criteria for sponsor of medicine or medical device

(1) A person meets the criteria for being the sponsor of a medicine or medical device if the Regulator is satisfied on reasonable grounds that all of the following apply:

(a) the person is—

(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 or a Crown organisation:

(b) in the case of a standard authorisation or provisional authorisation, the person does, or proposes to do, any of the following activities (other than on behalf of another person who meets the criteria in paragraph (a)):

(i) import the product or arrange for another person to do so:

(ii) manufacture the product in New Zealand for supply or export or arrange for another person to do so:

(c) in the case of an export authorisation, the person exports the product or arranges for another person to do so, or proposes to do either of those things (other than on behalf of another person who meets the criteria in paragraph (a)):

(d) the person is, or will be, able to comply with their obligations under this Act:

(e) the person consents to being the sponsor of the product:

(f) the person is a fit and proper person to be the sponsor of the product.

(2) For a person who is not the responsible manufacturer of the product to be able to meet the criterion in subsection (1)(d), the person must have a contractual relationship with the responsible manufacturer that the Regulator is satisfied on reasonable grounds—

(a) will enable the person to comply with their obligations under this Act; and

(b) meets any criteria in the rules about the nature of the contractual relationship and the matters that must be agreed.

Issuing market authorisations for NHPs

125 Application for market authorisation for NHP

(1) A person may apply to the Regulator for a standard authorisation or an export authorisation for an NHP.

(2) Rules made for the purposes of section 379 in relation to applications under this section must provide for the applicant—

(a) to assess (in accordance with any requirements in the rules) whether the criteria for issuing a market authorisation in section 127, other than section 127(1)(d) and (e), are met; and

(b) to make a declaration in the application that the applicant is satisfied on reasonable grounds that those criteria are met.

(3) The rules may (but are not required to) provide for the applicant to make such an assessment and declaration about the criteria in section 127(1)(d) and (e).

Guidance note

The procedural and administrative requirements in sections 379 to 386 apply to an application under this section.

126 Issue of market authorisation for NHP

(1) The Regulator may issue a market authorisation for an NHP of the kind sought to the person named in the application as the proposed sponsor if—

(a) the product meets the criteria for a market authorisation of an NHP in section 127; and

(b) the proposed sponsor meets the criteria for being the sponsor of an NHP in section 128; and

(c) the Regulator is satisfied that it is appropriate to issue the market authorisation.

(2) For the purpose of making the decision, the Regulator must accept the applicant's declaration referred to in section 125 as sufficient evidence of the matters declared unless there is evidence to the contrary.

(3) However, this does not limit the Regulator's powers relating to assessing applications (including the power to request information under section 380 or to reject the application under section 384).

(4) If a Crown organisation is to be the sponsor, the market authorisation must be issued to the Crown organisation in its own name (and not to the Crown).

Guidance note

Decisions under this section are reviewable under subpart 6 of Part 9.

127 Criteria for market authorisation of NHP

(1) An NHP meets the criteria for a market authorisation if the Regulator is satisfied on reasonable grounds that all of the following apply:

(a) the NHP ingredients in the product are all recognised NHP ingredients:

(b) there is reasonable and adequate evidence to demonstrate the safety and quality of the NHP:

(c) the NHP will meet any product standards that apply to it:

(d) if the sponsor proposes to make any health benefit claim of the kind referred to in section 63(3), the NHP meets the criteria in the rules for that claim:

(e) any custom health benefit claim that the sponsor proposes to make about the NHP is substantiated in accordance with section 62(5) and (6):

(f) if the application is for an export authorisation, the NHP will meet any export standards that apply to it:

(g) the NHP is not a prohibited product:

(h) any other criteria in the rules are met.

(2) In determining whether the criterion in subsection (1)(e) is met, the Regulator must apply any criteria, and comply with any other requirements, that they are required by section 392(3) to apply or comply with when making rules for the purposes of section 63.

128 Criteria for sponsor of NHP

(1) A person meets the criteria for being the sponsor of an NHP if the Regulator is satisfied on reasonable grounds that all of the following apply:

(a) the person is—

(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 or a Crown organisation:

(b) in the case of a standard authorisation, the person does, or proposes to do, any of the following activities (other than on behalf of another person who meets the criteria in paragraph (a)):

(i) import the NHP or arrange for another person to do so:

(ii) manufacture the NHP in New Zealand for supply or export or arrange for another person to do so:

(c) in the case of an export authorisation, the person exports the NHP or arranges for another person to do so, or proposes to do either of those things (other than on behalf of another person who meets the criteria in paragraph (a)):

(d) the person is, or will be, able to comply with their obligations under this Act:

(e) the person consents to being the sponsor of the NHP:

(f) the person is a fit and proper person to be the sponsor of the NHP.

(2) For a person who is not the responsible manufacturer of the product to be able to meet the criterion in subsection (1)(d), the person must have a contractual relationship with the responsible manufacturer that the Regulator is satisfied on reasonable grounds—

(a) will enable the person to comply with their obligations under this Act:

(b) meets any criteria in the rules about the nature of the contractual relationship and the matters that must be agreed.

Content and scope of market authorisations

129 Content of market authorisation

(1) A therapeutic product's market authorisation must set out all of the following:

Product details

(a) whether the product is a medicine, a medical device, or an NHP:

(b) a description of the product:

(c) in the case of a medicine or medical device, the purpose or indication for which it is authorised:

(d) in the case of a medicine, whether it is a prescription medicine, pharmacist medicine, pharmacy, or general-sale medicine:

Sponsor and manufacturer details

(e) the name and address of the sponsor:

(f) the name and address of the responsible manufacturer:

(g) the address of each place at which the product may be manufactured:

Health benefit claims

(h) if the product is an NHP,—

(i) which (if any) of any standard health benefit claims of the kind referred to in section 63(3) may be made about the NHP; and

(ii) the terms of any custom health benefit claims that may be made about the NHP:

Authorisation details

(i) what kind of market authorisation it is:

(j) the date on which it is issued and, if it is to take effect on a later date, that date:

(k) if it is a provisional authorisation, its expiry date (which must not be more than 2 years after it takes effect):

(l) any conditions imposed by the Regulator under section 136:

(m) any conditions, product standards, export standards, or other rules that are disapplied (*see* section 130):

Other details

(n) any other information required by the regulations.

(2) The purpose or indication for which a therapeutic product is authorised may be described by reference to any of the following matters or in any other way the Regulator thinks is appropriate:

(a) the disease, ailment, defect, injury, physiological process, or part of the anatomy in relation to which it may be used:

(b) the class of patients in relation to whom it may be used:

(c) the method of administration or use:

(d) the circumstances in which it may be used.

(3) The market authorisation may set out any other matters the Regulator thinks are appropriate.

130 Market authorisation may disapply rules relating to product

A market authorisation may disapply any of the following:

(a) a condition set out in the rules to which the authorisation would otherwise be subject under section 136:

(b) a product standard that would otherwise apply in relation to the product:

(c) an export standard that would otherwise apply in relation to the product.

131 Scope of market authorisation

(1) A market authorisation applies to—

(a) the product as described in the authorisation; and

(b) any subsequent changes in relation to the product that are minor changes (as defined in section 147).

(2) A market authorisation for a medicine or medical device authorises the product only for the authorised indications.

Guidance note

The sponsor must notify the Regulator of certain minor changes (*see* section 147).

132 Major change results in different product

(1) A **major change**, in relation to a therapeutic product with a market authorisation, means a change to the product itself or to any matter or information relating to the product that—

(a) is likely to have a significant impact on,—

(i) in the case of a medicine, its safety, quality, or efficacy; or

(ii) in the case of a medical device, its safety, quality, or performance; or

(iii) in the case of an NHP, its quality or safety; and

(b) the rules say is a major change.

(2) If a major change occurs, the changed product is 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).

Guidance note

As the changed product is a different therapeutic product, the original product's market authorisation does not cover it and a separate market authorisation is needed for the changed product.

However, the original product's market authorisation remains in force in relation to the original product.

133 Change of sponsor

(1) A market authorisation cannot be transferred from the sponsor to another person other than under subsection (2).

(2) The Regulator may, on application by the sponsor, transfer a market authorisation to a new sponsor if satisfied on reasonable grounds that the proposed new sponsor meets the criteria for being a sponsor in section 124 or 128.

(3) If the Regulator is not satisfied, they must refuse to transfer the authorisation.

Guidance note

Decisions under this section are reviewable under subpart 6 of Part 9.

Duration of market authorisations

134 Duration of market authorisation

(1) A market authorisation takes effect when it is issued or at any later time set out in it.

(2) It remains in force until the first of the following occurs:

(a) it is cancelled:

(b) if it is a provisional authorisation,—

(i) it expires:

(ii) the Regulator issues a standard authorisation for the product:

(c) if it is a standard authorisation or an export authorisation and it has an expiry date, it expires:

(d) if the regulations set out a maximum duration for the authorisation, that period expires:

(e) the authorisation lapses under section 135.

135 Market authorisation lapses on death, bankruptcy, or insolvency of sponsor

A market authorisation lapses if the sponsor,—

(a) in the case of an individual, dies or becomes bankrupt; or

(b) in the case of any other person, ceases to exist or becomes subject to an insolvency event (as defined in section 6 of the Financial Markets Conduct Act 2013).

Guidance note

If a market authorisation lapses, the Regulator may allow for continued use of stock that is already in the supply chain (*see* section 116).

Conditions on market authorisations

136 Conditions on market authorisation

(1) A market authorisation is subject to—

(a) any conditions set out in the rules; and

(b) any conditions imposed by the Regulator under subsection (2).

(2) The Regulator may impose any conditions they think are appropriate on a market authorisation—

(a) when issuing the authorisation; or

(b) at any time by varying the authorisation under section 137 or 138.

(3) In determining what conditions to impose on a provisional authorisation, the Regulator must have regard to the fact that the product's safety, quality, and efficacy or performance for its intended authorised indications have not been established to the standard required by section 123(1)(a).

(4) A condition cannot be imposed under subsection (1)(b) that is inconsistent with a condition set out in the rules, unless the condition in the rules is disapplied under section 130.

Guidance note

Decisions under this section are reviewable under subpart 6 of Part 9.

Variation of market authorisations

137 Variation of market authorisation on application by sponsor

(1) The Regulator may vary a market authorisation on application by the sponsor.

(2) However, a market authorisation cannot be varied—

(a) to change which product it authorises; or

(b) to change who the sponsor is.

(3) Sections 121 to 128 apply (with any necessary modifications) to the application.

(4) In complying with section 122, the Regulator is required to evaluate the product only to the extent of the proposed variation.

(5) The Regulator must serve notice of the variation on the sponsor.

(6) The variation takes effect when the notice is served or at any later time set out in it.

Guidance note

In relation to major changes to a product and changes of sponsor, *see* sections 132 and 133.

Decisions under this section are reviewable under subpart 6 of Part 9.

138 Variation of market authorisation by Regulator

(1) The Regulator may vary a market authorisation on their own initiative to do either of the following:

(a) change the conditions to which the authorisation is subject under section 136:

(b) if grounds to cancel the market authorisation exist, address the matters giving rise to those grounds.

(2) The Regulator must not do so unless they have given the sponsor an opportunity to comment.

(3) The Regulator must serve notice of the variation on the sponsor.

(4) The variation takes effect when the notice is served or at any later time set out in it.

Guidance note

Decisions under this section are reviewable under subpart 6 of Part 9.

Cancellation of market authorisations

139 Grounds to cancel market authorisation

There are **grounds to cancel** a therapeutic product's market authorisation if the Regulator is satisfied on reasonable grounds that any of the following apply:

(a) in the case of a medicine, its safety, quality, and efficacy for its intended authorised indications are no longer satisfactorily established:

(b) in the case of a medical device, its safety, quality, and performance for its intended authorised indications are no longer satisfactorily established:

(c) in the case of an NHP, there is no longer reasonable and adequate evidence to demonstrate its safety and quality:

(d) the likely risks associated with the product outweigh its likely benefits:

(e) the product does not conform to its market authorisation:

(f) the product does not meet the product standards and export standards that apply to it:

(g) the sponsor does not meet the criteria for being a sponsor in section 124 or 128:

(h) any other criteria for authorisation under section 123 or 127 are not met:

(i) any information in the application for the authorisation was misleading information:

(j) when determining whether to issue the authorisation, the Regulator used protected active ingredient information contrary to subpart 3:

(k) the sponsor has contravened a provision of this Act:

(l) the responsible manufacturer has contravened a provision of this Act:

(m) the product has ceased to be a therapeutic product or to be the type of therapeutic product it was when the market authorisation was issued:

(n) the product has become a prohibited product:

(o) any grounds to cancel the authorisation set out in the rules exist.

140 Regulator may cancel market authorisation if grounds exist

(1) The Regulator may cancel a therapeutic product's market authorisation if grounds to cancel the authorisation exist.

(2) The Regulator must not do so unless they have given the sponsor an opportunity to comment.

(3) However, subsection (2) does not apply if the Regulator is satisfied on reasonable grounds that the product directly or indirectly exposes any individual to a risk of death, serious injury, or serious illness.

(4) The Regulator must serve notice of the cancellation on the sponsor.

(5) The cancellation takes effect when the notice is served or at any later time set out in it.

Guidance note

If a market authorisation is cancelled, the Regulator may allow for continued use of stock that is already in the supply chain (*see* section 116).

Decisions under this section are reviewable under subpart 6 of Part 9.

141 Regulator may cancel market authorisation on application

(1) The Regulator may cancel a market authorisation on application by the sponsor.

(2) The Regulator must serve notice of the cancellation on the sponsor.

(3) The cancellation takes effect when the notice is served or at any later time set out in it.

Guidance note

If a market authorisation is cancelled, the Regulator may allow for continued use of stock that is already in the supply chain (*see* section 116).

Decisions under this section are reviewable under subpart 6 of Part 9.

Subpart 2—Obligations of sponsors

Guidance note

Not complying with a provision of this subpart may be an offence, a civil penalty contravention, or an infringement offence (*see* subparts 2 to 5 of Part 8).

142 Sponsor must ensure compliance with market authorisation

(1) The sponsor of a therapeutic product must—

(a) comply with the product's market authorisation; and

(b) ensure that the product conforms to its market authorisation; and

(c) if the market authorisation requires any other person to do, or not to do, something, ensure that the other person complies with the requirement.

(2) The market authorisation does not cease to be in force because of a contravention of this section.

Guidance note

Although non-compliance with the market authorisation does not cause the authorisation to cease to be in force, it provides a ground on which the Regulator may cancel it (*see* section 139).

143 Sponsor must ensure product meets product standards

(1) The sponsor of a therapeutic product must ensure that the product meets the product standards that apply to it.

(2) However, the sponsor is not required to ensure that the product meets a product standard if the market authorisation says the standard does not apply.

144 Sponsor must ensure product meets export standards

(1) The sponsor of a therapeutic product with an export authorisation must ensure that the product meets the export standards that apply to it.

(2) The sponsor of a therapeutic product with a standard authorisation or provisional authorisation must ensure that if the product is exported, it meets the export standards that apply to it.

(3) However, the sponsor is not required to ensure that the product meets an export standard if the market authorisation says the standard does not apply.

145 Sponsor must have surveillance and response system

(1) The sponsor of a therapeutic product must have in place a system for post-market surveillance and response for the product.

(2) The surveillance and response system must provide for the sponsor to—

(a) conduct surveillance of, —

(i) in the case of a medicine, its safety, quality, and efficacy; or

(ii) in the case of a medical device, its safety, quality, and performance; or

(iii) in the case of an NHP, its safety and quality; and

(b) respond to, and take action to address, issues relating to the matters referred to in paragraph (a)(i) to (iii) (whether identified through the sponsor's surveillance or otherwise).

(3) The surveillance and response system must—

(a) provide for surveillance and responses that are appropriate and proportionate, having regard to the likely benefits of, and risks associated with, the product; and

(b) comply with any requirements in the rules about the kind of surveillance and responses that are required or the content of the system.

(4) The sponsor must, in accordance with the surveillance and response system,—

(a) carry out surveillance of the product; and

(b) when appropriate, respond to safety, quality, efficacy, or performance issues.

(5) The sponsor must—

(a) conduct simulations or other tests of the system as and when required by the rules; and

(b) comply with any other requirements in the rules about the use of the surveillance and response system.

146 Sponsor must comply with rules

(1) The sponsor of a therapeutic product must comply with any requirements in the rules about any of the following:

(a) the safety, quality, and efficacy of medicines:

(b) the safety, quality, and performance of medical devices:

(c) the safety and quality of NHPs:

(d) product information and consumer information:

(e) identification and labelling:

(f) packages and packing:

(g) releasing products for supply:

(h) exporting therapeutic products:

(i) tracing and recall:

(j) quality assurance:

(k) record keeping and auditing:

(l) giving information or samples to the Regulator:

(m) the need to have regulatory liaison officers, who may be a regulatory liaison officer, and any other matters relating to them.

(2) However, the sponsor is not required to comply with a requirement set out in the rules—

(a) if the product's market authorisation says it does not apply; or

(b) to the extent that compliance with it would be contrary to the market authorisation.

(3) Rules made for the purposes of this section cannot impose qualification, training, and competency requirements for individuals who are sponsors or who work for them (*see instead* section 74).

(4) In this section, **regulatory liaison officer** means a worker of the sponsor whose duties include giving information and other assistance to the Regulator, overseas regulators, and overseas organisations to enable them to perform their functions and exercise their powers.

147 Sponsor must notify Regulator of certain minor changes

(1) The sponsor of a therapeutic product must notify the Regulator if—

(a) a minor change occurs in relation to the product; and

(b) the change is of a kind that the rules say must be notified under this section.

(2) A **minor change**, in relation to a therapeutic product, means a change to the product, or to any matter or information relating to the product, that is not a major change.

Guidance note

The requirements for notifying the Regulator are set out in section 387.

148 Sponsor of reportable product must notify Regulator of likely shortage

(1) If there are reasonable grounds to believe that demand in New Zealand for a reportable product is likely to exceed supply at any time in the next 6 months, the sponsor must notify the Regulator of the likely shortage.

(2) They must do so as soon as practicable after they become aware (or ought reasonably to have become aware) of the likely shortage, and in any event not more than—

(a) in the case of a critical-needs product, 4 days after that time; or

(b) otherwise, 10 working days after that time.

(3) This section does not apply if the sponsor has notified the Regulator under section 149 that they intend to cease importing or supplying the product.

Guidance note

The requirements for notifying the Regulator are set out in section 387.

149 Sponsor of reportable product must notify decision to stop supplying product

(1) If the sponsor of a reportable product decides to permanently stop supplying the product, they must notify the Regulator of that decision.

(2) They must do so,—

(a) in the case of a critical-needs product, at least 12 months before they intend to stop; or

(b) otherwise, at least 6 months before they intend to stop.

(3) However, if the sponsor cannot comply with subsection (2) because the decision is made less than 12 months or 6 months (as the case requires) before they intend to stop supply, they must notify the Regulator as soon as practicable after making the decision.

Guidance note

The requirements for notifying the Regulator are set out in section 387.

150 Sponsor not responsible for products imported without consent

This subpart does not apply to the sponsor of a therapeutic product in relation to a specific product that is imported without the sponsor's consent (whether or not the person importing it is allowed to do so).

Subpart 3—Protection of active ingredient information about innovative medicines

151 Interpretation

In this Act,—

active moiety means a 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 a market authorisation for a medicine if—

(a) the medicine contains an active ingredient; and

(b) prior to the application being made, no application has been made for a market authorisation for 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 is defined in section 152.

Guidance note

In relation to applications made under the Medicines Act 1981, *see also* clause 35 of Schedule 1.

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

(1) During the protection period for protected active ingredient information, the Regulator must not—

(a) disclose the information, unless section 153 allows them to do so; or

(b) use the information for the purposes of determining whether to issue any other market authorisation.

(2) When an innovative medicine application is made for a medicine, the **protection period** for the medicine's protected active ingredient information—

(a) starts when the Regulator first receives the application; and

(b) ends,—

(i) if the Regulator decides the application by issuing a market authorisation for the medicine, 5 years after the authorisation is issued; or

(ii) if the application is determined without a market authorisation being issued, when that happens.

(3) This section overrides any other provision in this Act that requires or allows the Regulator or any other person to disclose information, other than section 153.

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

Despite section 152, the Regulator may disclose or use protected active ingredient information during a protection period for the information if—

(a) the regulations allow the disclosure or use; or

(b) the applicant (or, if a market authorisation has been issued, 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

154 What licence may allow

(1) A licence may be granted under section 159 to allow the licensee to carry on 1 or more controlled activities.

(2) A licence allowing a person to carry on a controlled activity may also do either or both of the following:

(a) allow the licensee to do anything else specified in the licence that would otherwise contravene a provision of this Act:

(b) allow a person other than the licensee to do anything that the licence could allow the licensee to do.

155 Content of licence

(1) A licence must set out all of the following:

(a) the licensee's name and address:

(b) the controlled activities that the licence allows the licensee to carry on:

(c) anything else that the licence allows the licensee to do:

(d) for each other person who is allowed by the licence to do something,—

(i) their name and address (or if there is a class of other persons, a description of that class):

(ii) the controlled activities they are allowed to carry on:

(iii) anything else that the licence allows 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 licensed place:

(g) the names of the responsible persons for the licence:

(h) any conditions imposed by the Regulator and any disapplication of conditions set out in the rules (*see* section 170):

(i) its expiry date (*see* section 169):

(j) any other information required by the regulations.

(2) If, for the purposes of section 156(1)(b), a licence specifies that it does not permit persons who work for the licensee to do something, the licence may permit 1 or more of those workers to do so under subsection (1)(d) of this section.

(3) A **licensed place** means,—

(a) if the licence is a pharmacy licence, the places at, or vehicles from, which the licence allows 1 or more pharmacy activities to be carried on; or

(b) otherwise, if the licence allows controlled activities to be carried on or other things to be done only at certain places, each of those places.

Example

A pharmacy licence may identify licensed places individually or by class. It might also identify different places for different activities. So it might allow the licensee to do the following:

- compound, dispense, and supply medicines at the licensee's main shop at a specified address:
- dispense and supply medicines at any aged-care facility in a specified area:
- supply medicines from a pharmacy van in a specified area:
- supply, 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, for example, that medicines may be supplied at an aged-care facility only for patients who are residents of the facility.

156 Effect of licence

(1) A licence allows—

(a) the licensee to carry on the controlled activities and do any other things set out in it; and

(b) a person who works for the licensee and is acting within the scope of their actual or apparent authority to do anything that the licence allows the licensee to do, unless the licence specifies otherwise; and

(c) any other person specified in the licence to do the things set out in it for that person.

(2) However, the licence allows things to be done only—

(a) in relation to a therapeutic product covered by the licence; and

(b) if they are done in accordance with the terms and conditions of the licence.

(3) For a pharmacy licence, this section is subject to section 157.

Example

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

If Big Co manufactured medicine B, they would contravene section 70 because the licence does not allow that. If Big Co manufactured medicine A at a different factory, they would also contravene section 70 because the licence does not allow that.

If Big Co wants to be able to do something different from what their licence allows, they would need to get the licence varied (under section 171) or get a separate licence to do the other thing.

157 Effect of pharmacy licence: additional provisions

(1) This section modifies the effect of section 156(1)(a) and (b) in relation to a pharmacy licence (being a licence that allows the licensee to carry on a pharmacy business).

(2) Despite section 156(1)(a) and (b), a pharmacy licence—

(a) allows the licensee to carry on a pharmacy activity only to the extent that the activity is carried on, by or on behalf of the licensee, by an individual who is personally allowed to carry on that pharmacy activity (whether by sections 77 to 83 or otherwise); and

(b) does not allow any other worker in the business to carry on a pharmacy activity, unless the licence specifies (under section 155(1)(d)) that the worker is allowed to carry on that activity.

Guidance note

Generally, section 156(1)(a) and (b) allows a licensee and their workers to carry on the controlled activities set out in the licence. In the case of a pharmacy licence, this section limits what the licensee and workers can do.

Sections 77 to 83 allow pharmacists and pharmacy workers working in the business to carry on certain pharmacy activities.

158 Effect of licence allowing products without standard authorisation or provisional authorisation into supply chain

(1) This section applies if a licence—

(a) authorises a person to import or supply a therapeutic product that does not have a standard authorisation or provisional authorisation; and

(b) says that the product may be released into the supply chain in accordance with this section.

(2) If this section applies, this Act applies as if—

(a) the product had a standard authorisation or provisional authorisation; and

(b) in the case of a medicine or medical device, its authorised indications were those set out in the licence; and

(c) in the case of an NHP, its permitted health benefit claims were those identified or set out in the licence; and

(d) the licensee were the sponsor of the product.

159 Application and grant of licence

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

(2) The Regulator may grant a licence to the person named in the application as the proposed licensee if —

(a) the proposed licensee meets the criteria for being a licensee in section 160; and

(b) the criteria for a licence in section 161 are met; and

(c) the Regulator is satisfied that it is appropriate to grant the licence.

(3) If subsection (2)(a) to (c) is not met, the Regulator must refuse to grant a licence.

(4) If a Crown organisation is to be the licensee, the licence must be granted to the Crown organisation in its own name (and not to the Crown).

Guidance note

The procedural and administrative requirements in sections 379 to 386 apply to an application under this section.

Decisions under this section are reviewable under subpart 6 of Part 9.

160 Criteria for licensee

A person meets the criteria for being a licensee if the Regulator is satisfied on reasonable grounds that—

(a) the person is—

(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 or a Crown organisation; and

(b) the person is a fit and proper person to be a licensee.

161 Criteria for granting licence

(1) The criteria for granting a licence are met if the Regulator is satisfied on reasonable grounds that all of the following apply (or will apply if the licence is granted):

(a) the number of responsible persons for the licence is not less than the number required by the rules:

(b) each responsible person meets the criteria for being a responsible person in section 162:

(c) the relevant resources are adequate and suitable to ensure that—

(i) the likely risks associated with the controlled activities and other things that the licence allows to be done are able to be adequately managed; and

(ii) all persons who are allowed by the licence to do something are, or will be, able to comply with this Act:

(d) the relevant persons, collectively, have sufficient knowledge of—

(i) this Act and the licensee's obligations under it; and

(ii) the therapeutic products covered by the licence; and

(iii) each controlled activity or other thing that the licence allows to be carried on or done—

to enable the licensee to comply with this Act:

(e) each relevant person has sufficient knowledge of the matters referred to in paragraph (d) and their own obligations under the Act to enable them to comply with this Act:

(f) each relevant person and any other person allowed by the licence to do something is, or will be, able to comply with this Act:

(g) if the licence allows a person to conduct a clinical trial,—

(i) an ethics approval is in force for the trial; or

(ii) a relevant ethics approval entity has issued a certificate stating that an ethics approval is not required for the trial:

(h) if the licence allows a person to import a therapeutic product that does not have a standard authorisation or provisional authorisation (unless the product is to be imported for a clinical trial), there are special circumstances that justify allowing the product to be imported even though it does not have a standard authorisation or provisional authorisation:

(i) any other criteria in the rules are met.

Example

Special circumstances (referred to in subsection (1)(h)) might be that there is a shortage of a life-saving medicine and there is no alternative medicine with a standard authorisation or provisional authorisation.

(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 allowed by the licence or for complying with this Act; and

(b) the human and financial resources of the licensee and other persons allowed by the licence to do something.

162 Criteria for responsible person

A person meets the criteria for being a responsible person if the Regulator is satisfied on reasonable grounds that the person—

(a) is an individual; and

(b) is ordinarily resident in New Zealand; and

(c) consents to being a responsible person for the licence; and

(d) is a fit and proper person to be a responsible person; and

(e) meets any qualification, training, and competency requirements in the regulations.

Subpart 2—Permits

163 What permit may permit

(1) A permit may be granted under section 167 to allow the permit holder to do any of the following:

(a) import or supply a therapeutic product even though it does not have a standard authorisation or provisional authorisation:

(b) export a therapeutic product even though it does not have a market authorisation:

(c) carry on a controlled activity:

(d) anything else that would otherwise contravene a provision of this Act.

(2) A permit may also allow any other person to do anything referred to in subsection (1).

164 Content of permit

(1) A permit must set out all of the following:

(a) the permit holder's name and address:

(b) the things that the permit allows the permit holder to do:

(c) whether the permit extends to persons who work for the permit holder:

(d) for each other person who is allowed by the permit to do something,—

(i) their name and address (or, if there is a class of other persons, a description of that class):

(ii) the things that the permit allows them to do:

(e) the therapeutic products covered by the permit:

(f) if the permit allows 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 and any disapplication of conditions set out in the rules (*see* section 170):

(h) its expiry date (*see* section 169):

(i) any other information required by the regulations.

(2) If, under subsection (1)(c), a permit says that it does not extend to persons who work for the permit holder, the permit may, under subsection (1)(d), say that 1 or more of those workers are allowed to do something.

165 Effect of permit

(1) A permit allows—

(a) the permit holder to do the things set out in it; and

(b) if the permit extends to persons who work for the permit holder, a worker who is acting within the scope of their actual or apparent authority to do anything that the permit allows the permit holder to do; and

(c) any other person specified in the permit to do the things set out in it for that person.

(2) However, the permit allows things to be done only—

(a) in relation to a therapeutic product covered by the permit; and

(b) if they are done in accordance with the terms and conditions of the permit.

(3) A permit does not allow a person to do anything with a prohibited product unless the permit expressly says that it does.

166 Effect of permit allowing products without standard authorisation or provisional authorisation into supply chain

(1) This section applies if a permit—

(a) authorises a person to import or supply a therapeutic product that does not have a standard authorisation or provisional authorisation; and

(b) says that the product may be released into the supply chain in accordance with this section.

(2) If this section applies, this Act applies as if—

(a) the product had a standard authorisation or provisional authorisation; and

(b) in the case of a medicine or medical device, its authorised indications were those set out in the permit; and

(c) in the case of an NHP, its permitted health benefit claims were those identified or set out in the permit; and

(d) the permit holder were the sponsor of the product.

167 Application and grant of permit

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

(2) The Regulator may grant a permit to the person named in the application as the proposed permit holder if—

(a) the criteria for a permit in section 168 are met; and

(b) the Regulator is satisfied that it is appropriate to grant the permit.

(3) If subsection (2)(a) and (b) is not met, the Regulator must refuse to grant the permit.

(4) If a Crown organisation is to be the permit holder, the permit must be granted to the Crown organisation in its own name (and not to the Crown).

Guidance note

The procedural and administrative requirements in sections 379 to 386 apply to an application under this section.

Decisions under this section are reviewable under subpart 6 of Part 9.

168 Criteria for granting permit

The criteria for a permit are met if the Regulator is satisfied on reasonable grounds that all of the following apply (or will apply if the permit is granted):

(a) the permit holder is a fit and proper person to hold the permit:

(b) any other person who is allowed by the permit to do something is a fit and proper person to do the thing:

(c) the permit holder and any other person who is allowed by the permit to do something are, or will be, able to comply with this Act:

(d) all of the things that the permit allows to be done will be done in such a way that the likely risks associated with them are adequately managed:

(e) if the permit allows a person to conduct a clinical trial,—

(i) an ethics approval is in force for the trial; or

(ii) a relevant ethics approval entity has issued a certificate stating that an ethics approval is not required for the trial:

(f) if the permit allows a person to import a therapeutic product that does not have a standard authorisation or provisional authorisation (unless it is to be imported for the purposes of a clinical trial), there are special circumstances that justify allowing the product to be imported even though it does not have a standard authorisation or provisional authorisation:

(g) if the permit relates to a prohibited product, any criteria in the regulations about carrying out activities with the prohibited product are met:

(h) any other criteria in the rules are met:

(i) granting the permit is a necessary or desirable way to address the matter that gave rise to the permit:

(j) the extent of the permit is not broader than is reasonably necessary to address that matter.

Subpart 3—Provisions applying to licences and permits

Duration of licence or permit

169 Duration of licence or permit

(1) A licence—

(a) takes effect when it is granted or at any later time set out in it; and

(b) remains in force for 5 years or for any shorter period set out in it (unless it is cancelled before then).

(2) A permit—

(a) takes effect when it is granted or at any later time set out in it; and

(b) remains in force for 2 years or for any shorter period set out 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

170 Conditions on licence or permit

(1) A licence or permit is subject to—

(a) any conditions set out in the rules; and

(b) any conditions imposed by the Regulator under subsection (3).

(2) However, a licence or permit is not subject to a condition set out in the rules if the licence or permit disapplies the condition.

(3) The Regulator may impose on a licence or permit any conditions they think are appropriate—

(a) when the licence or permit is granted; or

(b) at any time by varying the licence or permit under section 171.

Guidance note

Decisions under this section are reviewable under subpart 6 of Part 9.

Variation of licence or permit

171 Variation of licence or permit

(1) The Regulator may vary a licence or permit (including any conditions to which it is subject under section 170) on their own initiative or on application by the licensee or permit holder.

(2) However, the Regulator must not do so on their own initiative unless they have given the licensee or permit holder an opportunity to comment.

(3) The Regulator must serve notice of the variation on the licensee or permit holder.

(4) The variation takes effect when the notice is served or at any later time set out in it (but that does not affect the duration of the licence or permit).

Guidance note

Decisions under this section are reviewable under subpart 6 of Part 9.

Suspension and cancellation of licence or permit

172 Grounds to suspend or cancel licence

(1) There are **grounds to suspend or cancel** a licence if the Regulator is satisfied on reasonable grounds that any of the following apply:

(a) the criteria for granting a licence in section 161 are not met:

(b) the licensee has contravened a provision of this Act:

(c) any other person who is allowed by the licence to do something has contravened a provision of this Act:

(d) any of the controlled activities or other things that the licence allows to be carried on or done are being done in such a way that the likely risks associated with them are not being adequately managed:

(e) any information in the application for the licence was misleading information:

(f) the licensee has ceased to carry on all controlled activities that the licence allows them to carry on and does not intend to resume doing so before the licence's expiry date:

(g) if the licence allows a person to conduct a clinical trial, the ethics approval for the trial or the certificate referred to in section 161(1)(g)(ii) is not complied with or is revoked:

(h) any grounds to suspend or cancel the licence set out 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 the licence allows them to do.

173 Grounds to suspend or cancel permit

(1) There are **grounds to suspend or cancel** a permit if the Regulator is satisfied on reasonable grounds that any of the following apply:

(a) the criteria for granting a permit in section 168 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 who is allowed by the permit to do something has contravened a provision of this Act:

(e) any of the things that the permit allows to be done are being done in such a way that the likely risks associated with them are not being adequately managed:

(f) the permit holder has ceased to do all the things that the permit allows them to do 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) if the permit allows a person to conduct a clinical trial, the ethics approval for the trial or the certificate referred to in section 168(e)(ii) is not complied with or is revoked:

(i) any grounds to suspend or cancel the permit set out 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 the permit allows them to do.

174 Regulator may suspend or cancel if grounds exist

(1) The Regulator may suspend or cancel a licence or permit if grounds to suspend or cancel it exist.

(2) A suspension may be for a specified period (not exceeding 6 months) or until a specified requirement is met.

(3) However, the Regulator may suspend a licence or permit again if grounds to suspend or cancel it continue to exist.

(4) The Regulator must serve notice of the suspension or cancellation on the licensee or permit holder.

(5) If the licence or permit allows a person other than the licensee or permit holder to do something, the Regulator must take reasonable steps to notify them of the suspension or cancellation.

Guidance note

Decisions under this section are reviewable under subpart 6 of Part 9.

175 Procedure to suspend or cancel

(1) The Regulator must not suspend or cancel a licence or permit under section 174 unless they have given the licensee or permit holder an opportunity to comment.

(2) This section does not apply if the Regulator is satisfied on reasonable grounds that the suspension or cancellation is necessary because of a significant risk to any individual of death, serious injury, or serious illness.

176 Regulator may suspend or cancel on application

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

(2) The Regulator must serve notice of the suspension or cancellation on the licensee or permit holder.

(3) If the licence or permit allows a person other than the licensee or permit holder to do something, the Regulator must take reasonable steps to notify them of the suspension or cancellation.

Guidance note

Decisions under this section are reviewable under subpart 6 of Part 9.

177 Duration of suspension

The suspension of a licence or permit by the Regulator—

(a) takes effect when the notice under section 174 or 176 is served or at any later time set out in it; and

(b) remains in force until—

(i) the specified suspension period (if any) expires; or

(ii) the suspension is lifted under section 178.

178 Lifting of suspension

(1) If the Regulator suspends a licence or permit, they—

(a) may lift the suspension early if satisfied on reasonable grounds 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 on reasonable grounds that the requirement has been met.

(2) The Regulator may lift the suspension on their own initiative or on application by the licensee or permit holder.

(3) The Regulator must serve notice of the lifting of the suspension on the licensee or permit holder.

(4) If the Regulator notified another person of the suspension, the Regulator must take reasonable steps to notify them of the lifting of the suspension.

Guidance note

Decisions under this section are reviewable under subpart 6 of Part 9.

179 Effect of suspension or cancellation

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

(2) The cancellation of a licence or permit by the Regulator takes effect when the notice under section 174 or 176 is served or at any later time set out in it.

Transfer of licence or permit

180 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 181.

181 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 their death.

(2) If a licensee or permit holder becomes bankrupt, the licence or permit is transferred to the Official Assignee 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 when the insolvency event occurs.

(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 10 working days after whichever of the following occurs first:

(a) the person becomes aware (or ought reasonably to have become aware) that the licence or permit has transferred to them:

(b) anything that is authorised by the licence or permit is done after the transfer occurs.

Guidance note

The requirements for notifying the Regulator are set out in section 387.

Subpart 4—Obligations of licensees, permit holders, and responsible persons

Guidance note

Not complying with a provision of this subpart may be an offence, a civil penalty contravention, or an infringement offence (*see* subparts 2 to 5 of Part 8).

182 Licensee must ensure responsible person has authority and resources

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.

183 Licensee or permit holder must ensure health practitioner or veterinarian has authority and resources

A licensee or permit holder must ensure that,—

(a) in carrying on any controlled activities or doing anything else that the licence or permit allows, a health practitioner or veterinarian who works for them has sufficient authority and resources to enable the practitioner or veterinarian to act professionally; and

(b) the licensee's or permit holders's processes and procedures are not designed or implemented in a way that might reasonably be expected to induce a health practitioner or veterinarian to act unprofessionally.

184 Licensee, permit holder, or senior manager must not induce health practitioner or veterinarian to act unprofessionally

A licensee, permit holder, or senior manager of a licensee or permit holder must not engage in conduct with the intention of inducing a health practitioner or veterinarian who works for the licensee or permit holder to act unprofessionally.

185 Licensee and permit holder must comply with qualification, training, and competency requirements

(1) A licensee or permit holder,—

(a) if they are an individual, must not carry on a qualifying activity unless they meet the qualification, training, and competency requirements for the activity; and

(b) must ensure that no person working for them carries on a qualifying activity unless that person meets the qualification, training, and competency requirements for the activity.

(2) An activity that is, or is part of, something that a licence or permit allows to be done is a **qualifying activity** if the regulations say it may be carried on only by a person who meets the qualification, training, and competency requirements in the regulations.

186 Responsible person must report non-compliance

(1) This section applies if a responsible person for a licence has reason to believe 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 promptly notify the licensee of their belief and the reasons for 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 constituting the contravention continues.

(4) A responsible person who, in good faith, notifies a licensee or the Regulator under this section is not liable to any civil, criminal, or disciplinary proceeding because of doing so.

(5) 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 or undertaking:

(d) a responsible person for the licence:

(e) any other person who is allowed by the licence to do something.

Guidance note

The requirements for notifying the Regulator are set out in section 387.

187 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 under this Act, or complies with them in a particular way; or

(b) to prevent the responsible person from complying with those obligations or from complying with them in a particular way; or

(c) to induce the responsible person to comply with those obligations in a particular way or to not comply with them.

(4) In this section, **comply** includes has complied, is complying, or proposes to comply.

188 Responsible person must comply with rules

(1) A responsible person for a licence must comply with any requirements in the rules about any of the following:

(a) quality control and assurance requirements relating to the controlled activities that the licence allows to be carried on:

(b) record keeping and auditing:

(c) giving information to the Regulator:

(d) giving information and other assistance to sponsors to enable them to comply with their obligations under this Act:

(e) tracing and recall:

(f) post-market surveillance and response:

(g) quality assurance:

(h) oversight of the day-to-day operation of the activities of the licensee.

(2) Rules made for the purposes of this section cannot impose qualification, training, and competency requirements for responsible persons or other individuals who work for the licensee (*see instead* section 185).

189 Pharmacy licensee must ensure pharmacy activities are carried on by persons allowed to do so

(1) The licensee of a pharmacy licence must ensure that a pharmacy activity is carried on at a licensed place only if—

(a) it is carried on by a pharmacist who is allowed to carry on the activity; or

(b) it is carried on—

(i) by a qualified pharmacy worker who is allowed to carry on the activity; and

(ii) while a pharmacist is present at the licensed place.

(2) However, subsection (1)(b)(ii) does not apply if the rules made for the purposes of section 83(2)(c) allow the worker to carry on the activity without a pharmacist being present.

Guidance note

A qualified pharmacy worker is allowed to carry on an activity only if they do so under the supervision of a pharmacist (*see* section 83).

Part 6
Other prohibited conduct

Guidance note

Not complying with a provision of this Part may be an offence, a civil penalty contravention, or an infringement offence (*see* subparts 2 to 5 of Part 8).

Tampering

190 Tampering with therapeutic product

(1) A person must not tamper with a therapeutic product.

(2) A person must not—

(a) threaten to tamper with a therapeutic product; or

(b) claim to have tampered with a therapeutic product.

(3) To **tamper with** a therapeutic product means—

(a) to interfere with any of the following:

(i) the product itself:

(ii) its manufacturing process:

(iii) its performance:

(iv) its identification or labelling:

(v) its package:

(vi) its product information or consumer information; and

(b) to do so in a way that adversely affects, or might reasonably be expected to affect, any of the following:

(i) in the case of a medicine, its safety, quality, or efficacy:

(ii) in the case of a medical device, its safety, quality, or performance:

(iii) in the case of an NHP, its quality or safety:

(iv) in any case, how the product is used.

(4) However, doing something referred to in subsection (3) is not tampering with a therapeutic product if—

(a) it is done by a person who is lawfully carrying on a supply chain activity; and

(b) doing so is a normal part of carrying on that activity.

191 Supply chain activity with tampered-with products

(1) A person in the supply chain must not carry on a supply chain activity with a therapeutic product that has been tampered with.

(2) A person must not manufacture a medicine containing an API that has been tampered with.

192 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 has tampered with a therapeutic product; or

(b) a person is proposing to do so; or

(c) there is a risk that a person has done so or is proposing to do so.

(2) Subsection (1) applies even if—

(a) the product is not in person A's possession:

(b) the product does not yet exist:

(c) person A does not know the identity of the tamperer.

(3) A person who, in good faith, notifies the Regulator under this section is not liable to any civil, criminal, or disciplinary proceeding because of doing so.

Guidance note

The requirements for notifying the Regulator are set out in section 387.

Misrepresentation

193 Misrepresentation about therapeutic product

(1) A person must not make a misrepresentation about a therapeutic product.

(2) A person makes a **misrepresentation about a therapeutic product** if they represent (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 of a particular kind or with a particular status under this Act.

Example

The following are examples of representations that a product is of a particular kind or with a particular status:

(a) that it is an NHP:

(b) that it has a market authorisation:

(c) that it is a prescription medicine:

(d) that it has a particular authorised indication:

(e) that it is a rongoā product:

(f) that it is not a prohibited product.

194 Holding out misrepresentation

(1) A person must not make a holding out misrepresentation.

(2) A person makes a **holding out misrepresentation** if they represent (expressly or impliedly) that they or another person are any of the following when they are not:

(a) the sponsor of a therapeutic product:

(b) a licensee or permit holder:

(c) allowed to carry on a supply chain activity:

(d) a person of a particular kind or with a particular status under this Act:

(e) allowed by this Act do something or to do something in a particular way.

Health benefit claims

195 Impermissible health benefit claims about NHPs

(1) The sponsor of an NHP with a market authorisation, or the de facto sponsor of an NHP that does not have a market authorisation, must not make a health benefit claim about the NHP unless—

(a) it is a permitted health benefit claim for the NHP; and

(b) it is made in accordance with any requirements in the rules about how health benefit claims may be made.

(2) A person is the **de facto sponsor** of an NHP that does not have a market authorisation if they meet the criterion in section 128(1)(b) or (c) for being the sponsor of the NHP.

Advertising

196 Advertisement, communication, and distribute

(1) An **advertisement** for a therapeutic product means a communication made for the purpose of promoting the product.

(2) A **communication** means a communication made in any way whatsoever (including, for example, by an individual in person, using a physical object, in print, or using any kind of information or communications technology).

(3) However, the following are not advertisements:

(a) a public safety announcement made under section 239:

(b) a recall order:

(c) a statement, approved by the chief executive of the Ministry, that is made as part of a public health campaign:

(d) the pharmaceutical schedule (as defined in section 4 of the Pae Ora (Healthy Futures) Act 2022):

(e) a communication that a person must make under this Act or any other law (as long as it complies with the law that requires it to be made):

(f) a communication of a kind set out in the regulations.

(4) To **distribute** includes to make available to, or otherwise bring to the notice of, the public or a section of the public.

197 Advertising

(1) A person in New Zealand must not distribute an advertisement for a therapeutic product unless,—

(a) if the advertisement is distributed—

(i) in New Zealand, the product has a standard authorisation or provisional authorisation; or

(ii) outside New Zealand, the product has a market authorisation; and

(b) the advertisement complies with the advertisement requirements in subsection (2); and

(c) the advertisement is distributed in a way that complies with any requirements in the regulations about how the advertisement is distributed.

(2) The **advertisement requirements**, for an advertisement, are all of the following:

(a) it must contain the name of the person who is using the advertisement to promote the product:

(b) it must contain any information required by the rules or the regulations:

(c) it must not contain any information that is, directly or by implication, inconsistent with the product's market authorisation:

(d) in the case of an advertisement for a medicine or medical device, it must not promote the product, directly or by implication, for an off-label use:

(e) in the case of an advertisement for an NHP, it must not make a health benefit claim that is not a permitted health benefit claim for the NHP:

(f) it must not contain any misleading information:

(g) it must meet any standards set out in the regulations.

(3) Subsections (1)(a) and (2)(c) do not apply if—

(a) the regulations allow the product to be advertised without it having a market authorisation; or

(b) the product is an NHP that is manufactured and supplied without a market authorisation in reliance on—

(i) section 112 (rongoā); or

(ii) section 115 (personalised NHPs); or

(c) a licence or permit allows the person to distribute the advertisement; or

(d) the product is an API.

(4) Subsection (2)(d) does not apply if the regulations allow the product to be advertised for the off-label use.

(5) Regulations made for the purpose of subsection (1)(c)—

(a) may (without limitation) relate to any of the following:

(i) the form of an advertisement:

(ii) how an advertisement is distributed:

(iii) to whom an advertisement is distributed; and

(b) may have the effect of prohibiting the distribution of advertisements for a specified class of therapeutic products to a specified class of persons or in specified circumstances.

(6) A person in New Zealand must not distribute an advertisement for a prohibited product.

Improper inducements to health practitioners or veterinarians

198 Improper inducement to health practitioner or veterinarian

(1) A relevant person must not give a benefit, or offer or agree to give a benefit, to a health practitioner or veterinarian with the intention of—

(a) inducing the practitioner or veterinarian to make a favourable clinical decision about a therapeutic product; or

(b) rewarding the practitioner or veterinarian for making such a decision.

(2) A health practitioner or veterinarian must not accept, or ask for, a benefit that would contravene subsection (1).

(3) A health practitioner or veterinarian makes a **favourable clinical decision** about a therapeutic product if they make a clinical decision that the product is appropriate for a patient or give favourable advice about the product to a patient.

(4) In this section, **relevant person** means any of the following:

(a) the sponsor of a therapeutic product:

(b) a supplier of a therapeutic product:

(c) the licensee of a pharmacy business:

(d) a senior manager of a person referred to in paragraph (a), (b), or (c).

Preparatory and supporting conduct

199 Agreeing or offering to carry on supply chain activity unlawfully

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.

200 Obtaining therapeutic product when supply is unlawful

A person (**person A**) must not, in the course of a business or undertaking, obtain a therapeutic product from another person (**person B**) if it would be unlawful under this Act for person B to supply the product to person A.

Conduct relating to information and Regulator's powers

201 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) In this section, **required record** means a record that a person is required under this Act to make or keep.

202 Misleading information to Regulator or inspector

A person must not give information to the Regulator or an inspector for the purposes of this Act if it is misleading information.

203 Compliance with regulatory or investigative requirement

(1) A person who is required to do something under subpart 2 of Part 7 (regulatory powers) or subpart 1 of Part 8 (investigative powers), other than section 246, must do so.

(2) A person who is required under section 246 to give their name and address or supporting evidence to an inspector must do so.

204 Obstructing Regulator or inspector

A person must not obstruct the Regulator or an inspector in performing their functions or exercising their powers under this Act.

Part 7
Regulatory matters

205 Application of Part to products without market authorisation and misrepresented products

(1) In relation to a therapeutic product that does not have a market authorisation, a reference in this Part (other than subpart 5) to the product's **sponsor** is taken to refer to,—

(a) if the responsible manufacturer meets the criterion in section 124(1)(a) or 128(1)(a), that person; or

(b) if paragraph (a) does not apply but another manufacturer meets that criterion, that person; or

(c) if neither paragraph (a) nor paragraph (b) applies, the importer of the product.

(2) However,—

(a) if, as a result of subsection (1), the Regulator is required to do something in relation to a person referred to in subsection (1) (such as give them information); and

(b) after making reasonable efforts to do so, the Regulator is unable to identify or locate the person,—

the Regulator is not required to comply with that requirement.

(3) If a product is misrepresented to be a therapeutic product, this Part applies (with any necessary modifications) as if the product were a therapeutic product that did not have a market authorisation.

Guidance note

In relation to misrepresentation, *see* section 193.

Subpart 1—Post-market surveillance and response, and compliance monitoring

206 Post-market surveillance and response

(1) The Regulator must have in place a post-market surveillance and response system for all therapeutic products that have a market authorisation or that are otherwise lawfully in the supply chain (other than rongoā products that do not have a market authorisation).

(2) The surveillance and response system must provide for the Regulator to—

(a) conduct surveillance of—

(i) the safety, quality, and efficacy of medicines and APIs; and

(ii) the safety, quality, and performance of medical devices; and

(iii) the safety and quality of NHPs; and

(b) respond to, and take action to address, issues relating to the matters referred to in paragraph (a)(i) to (iii) (whether identified through the Regulator's surveillance or otherwise).

(3) The Regulator must ensure that the system—

(a) provides for surveillance and responses that are appropriate and proportionate having regard to the likely benefits of, and risks associated with, the products to which they apply; and

(b) complies with any requirements in the regulations about the kind of surveillance and responses that are required or the content of the system.

(4) The Regulator must—

(a) carry out surveillance of therapeutic products in accordance with the system; and

(b) when appropriate, respond to safety, quality, efficacy, or performance issues in accordance with the system.

(5) In carrying out their surveillance and response, the Regulator must comply with any requirements in the regulations about how that must be done.

207 Compliance monitoring

The Regulator must have in place a system for monitoring the compliance with this Act by the following persons:

(a) sponsors:

(b) licensees, permit holders, and responsible persons:

(c) persons in the supply chain:

(d) other persons to whom this Act applies.

Subpart 2—Regulatory powers

208 Exercising powers for regulatory purposes

Exercising a power for **regulatory purposes** means exercising the power for the purpose of enabling the Regulator to do any of the following:

(a) perform their post-market surveillance and response function under section 206:

(b) perform their compliance monitoring function under section 207:

(c) otherwise perform their functions and exercise their powers under this Act.

209 Power to require person to give information

(1) An inspector may, by written notice, require a person who is any of the following (**person A**) to give the Regulator any information that they reasonably need for regulatory purposes:

(a) the sponsor of a therapeutic product:

(b) a person in the supply chain:

(c) a licensee or permit holder:

(d) a person (other than the licensee or permit holder) who is allowed by a licence or permit to do something:

(e) a senior manager of a person referred to in paragraphs (a) to (d):

(f) a responsible person for a licence:

(g) a regulatory liaison officer (as defined in section 146):

(h) a person who was a person referred to in paragraphs (a) to (g) at a material time.

(2) The information required may include any of the following:

(a) information that is in person A's possession or control:

(b) information that could be compiled from information that is in person A's possession or control (for example, statistics):

(c) information to be obtained by person A for the purpose of complying with the requirement (for example, a report from a verification body).

(3) However, an inspector must not require person A to give information that is not already in person A's possession or control unless the inspector is satisfied

on reasonable grounds that it is reasonable to require person A to compile or obtain the information.

(4) An inspector must not require person A to give personal information (relating to any person) unless the inspector is satisfied on reasonable grounds that the information required by the Regulator could not reasonably be obtained without the personal information being disclosed by person A.

(5) The notice—

(a) must set out the date by which it must be complied with (which must allow person A a reasonable time to comply); and

(b) may include any other requirements the inspector thinks are appropriate.

Guidance note

A person given a notice under this section must comply with it (*see* section 203).

210 Power to require samples and testing

(1) For regulatory purposes an inspector may, by written notice, require the sponsor of a therapeutic product to do any of the following:

(a) take a sample of the product, have it tested, and give the results of the test to the Regulator:

(b) in the case of a medical device that produces an output, test the device by using it to produce a sample output, have that sample tested, and give the results of the test to the Regulator:

(c) give the Regulator a sample of the product, or a sample of a device's output, for testing.

(2) The required sample must not be more than the smallest sample reasonably needed for the purpose for which it is required.

(3) A notice requiring the sponsor to have something tested—

(a) may require the testing to be done by a recognised testing entity (as defined in section 358) or by a specific recognised testing entity; and

(b) must not require the testing to be done by a person who is not a recognised testing entity.

(4) A sample given to the Regulator for testing may be tested only by a recognised testing entity.

(5) The notice—

(a) must set out the date by which it must be complied with (which must allow person A a reasonable time to comply); and

(b) may set out any other requirements the inspector thinks are appropriate.

(6) A sample given to the Regulator under this section is taken to have been seized by the Regulator during an investigation.

Guidance note

A person given a notice under this section must comply with it (*see* section 203).

Sections 247 to 249 apply to things that have been seized by the Regulator.

211 Power of entry

(1) For regulatory purposes an inspector may, at any reasonable time, enter a place where any of the following is, or was at a material time, being carried on:

(a) a supply chain activity:

(b) an activity that a licence or permit allows to be carried on.

(2) When entering the place, the inspector may—

(a) be accompanied and assisted by any other person the inspector reasonably needs to assist them; and

(b) bring with them any equipment they reasonably need.

(3) If, in order to get to the place, the inspector reasonably needs to enter another place, the inspector may do so after taking steps to obtain the consent of the occupier of the other place.

(4) However, subsections (1) to (3) are subject to section 212.

(5) When entering or at a place where there are anti-contamination, biosecurity, safety, or similar measures in place, an inspector and anyone accompanying them must—

(a) comply with all reasonable requests from the occupier in relation to those measures; and

(b) otherwise take all practicable steps to comply with those measures.

212 Special requirements at certain places

(1) An inspector may enter the following places (the **restricted place**) only with the consent of an occupier or under a search warrant:

(a) a home:

(b) a marae or a building associated with a marae:

(c) a treatment room or consulting room while a patient or client is present.

(2) When at a marae or building associated with a marae, the inspector must take account of the kawa of the marae so far as practicable in the circumstances.

(3) When at a treatment room or consulting room while a patient or client is present, the inspector must take account of the patient's or client's privacy and well-being so far as practicable in the circumstances.

Obtaining and issuing warrant

(4) An issuing officer may, on application by an inspector, issue a search warrant if satisfied that there are reasonable grounds to believe that the restricted place—

(a) is a place referred to in section 211(1); or

(b) is the only practicable means by which an inspector can enter a place referred to in section 211(1).

(5) The inspector—

(a) may make the application only if the Regulator is satisfied that the grounds for issuing a search warrant set out in subsection (4) exist; and

(b) must make the application in accordance with subpart 3 of Part 4 of the Search and Surveillance Act 2012.

(6) A warrant issued under this section authorises an inspector to enter the restricted place only for the purposes of exercising their powers under section 213.

(7) In this section,—

consulting room means a room or place—

(a) where an NHP practitioner (as defined in section 115) carries on consultations with their clients; or

(b) where a rongoā practitioner provides a rongoā service or activity to their clients

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

treatment room means a part of a hospital, health care facility, or other place where patients are treated.

213 Inspector's powers having entered place

(1) An inspector who has entered a place referred to in section 211(1) (under that section or section 212) may exercise a power under this section for regulatory purposes.

(2) The inspector may do any of the following:

(a) inspect the place and anything found there that relates to any of the following:

(i) a supply chain activity carried on at the place:

(ii) an activity that a licence or permit allows to be carried on at the place:

(iii) therapeutic products that are or were at the place:

(b) examine anything referred to in paragraph (a):

(c) test any equipment, process, or procedure that relates to anything referred to in paragraph (a) (including by operating any equipment):

(d) test any therapeutic product found at the place (including, in the case of a medical device, by operating the device):

(e) take samples of any of the following:

(i) any therapeutic products found at the place:

(ii) the output of any medical devices found at the place (such as an X-ray from an X-ray machine):

(f) test or take samples of any substance found at the place:

(g) make records or recordings of things at or being done at the place:

(h) copy documents or otherwise make copies of information produced under subsection (3).

(3) The inspector may require any of the persons referred to in section 209(1) who are present at the place (or, if none of them are present, the person in charge of the place) to—

(a) produce information relating to anything referred to in subsection (2):

(b) keep any part of the place or anything at the place in an unaltered state for a reasonable period (for example, until the inspector is able to take samples).

(4) For the purpose of doing anything referred to in subsection (2) or (3), the inspector may do any of the following:

(a) use any equipment (whether at the place or brought with them under section 211(2)) that they reasonably need:

(b) require any of the persons referred to in section 209(1) who are present at the place (or, if none of them are present, the person in charge of the place) to assist the inspector.

(5) A sample taken under subsection (2)—

(a) must not be more than the smallest sample reasonably needed for the purpose for which it is required; and

(b) may be removed from the place and tested by a recognised testing entity (as defined in section 358).

Guidance note

A person who is required by an inspector to do something must do it (*see* section 203).

214 Inspector to identify themselves and give notice of search

(1) When entering a place under this subpart, an inspector must take reasonable steps to find the person in charge of the place, identify themselves as an inspector, and inform the person of the purpose of the entry.

(2) If unable to find a person in charge of the place, before leaving the place, the inspector must leave a written notice setting out all of the following:

(a) the inspector's name and a means of contacting them and the Regulator:

(b) that they are an inspector under this Act:

(c) that they entered the place:

(d) the date and time of their entry and departure:

(e) the reasons for entering the place.

(3) However, an inspector is not required to comply with this section if—

(a) it is not practicable to do so; or

(b) the inspector is satisfied on reasonable grounds that doing so would defeat the purpose for which the function or power is being performed or exercised.

Guidance note

Section 357 also requires an inspector to produce their identification card on request.

215 Imported consignments may be detained pending testing

(1) If an inspector exercises a power under section 210 in relation to a therapeutic product that is subject to the control of Customs, the Regulator may direct Customs to detain the product while the testing is carried out.

(2) Customs must detain the product and keep it subject to the control of Customs until the first of the following occurs:

(a) the Regulator notifies Customs that the product no longer needs to be detained:

(b) the product is seized as referred to in section 247(1)(a):

(c) 80 working days have expired after the day on which the direction was given.

(3) Section 159 of the Search and Surveillance Act 2012 applies to the detained product as if it had been seized by the Regulator.

216 Privilege against self-incrimination, etc

Nothing in this subpart affects the application of sections 53 to 67 of the Evidence Act 2006.

Subpart 3—Regulatory orders

Guidance note

Not complying with a provision of this subpart may be an offence, a civil penalty contravention, or an infringement offence (*see* subparts 2 to 5 of Part 8).

Recall orders

217 Recall order

(1) The Regulator may make a recall order for a therapeutic product if satisfied on reasonable grounds that the continued availability of the product directly

or indirectly creates or increases a significant risk to personal health or public health.

(2) A **recall order** is an order directing the product's sponsor or a person in the supply chain to do any 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 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) removing the product from the supply chain; or

(ii) reducing the risk to personal health or public health.

(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.

218 Compliance with recall order

(1) A person who has been served with a recall order by the Regulator must comply with it.

(2) If a recall order includes a prohibition under section 217(3), a person in the supply chain who has been served with a copy of the order by the product's sponsor must also comply with the order.

Premises restriction order

219 Premises restriction order

(1) The Regulator may make a premises restriction order for a place or vehicle in relation to a supply chain activity if satisfied on reasonable grounds that the use of the place or vehicle for the activity directly or indirectly exposes any individual to a risk of death, serious injury, or serious illness.

(2) A **premises restriction order** is an order prohibiting or restricting the use, in the course of a business or undertaking, of a specified place or vehicle (or part of a place or vehicle) for, or in relation to, the carrying on of a specified supply chain activity.

220 Compliance with premises restriction order

A person who has been served with a premises restriction order by the Regulator—

(a) must comply with it; and

(b) if they are an owner or occupier of the place or vehicle, must not permit it to be used in contravention of the order.

Advertising remediation order

221 Advertising remediation order

(1) The Regulator may make an advertising remediation order if satisfied on reasonable grounds that a person (the **advertiser**) has distributed, or caused the distribution of, an advertisement for a therapeutic product in contravention of section 197.

(2) An **advertising remediation order** is an order directing the advertiser, or a person involved in the distribution of the advertisement, to do any 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 any risk to personal health or public health.

222 Compliance with advertising remediation order

A person who has been served with an advertising remediation order by the Regulator must comply with it.

Directions orders

223 Directions order

(1) The Regulator may make a directions order in relation to a therapeutic product if satisfied on reasonable grounds that—

(a) the product directly or indirectly exposes any individual to a risk of death, serious injury, or serious illness; and

(b) making the order is a necessary or desirable way to address that risk; and

(c) the extent of the order is not broader than is reasonably necessary to address that risk.

(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.

(3) A directions order must set out the date on which it expires, which must not be more than 12 months after it is made.

224 Compliance with directions order

A person who has been served with a directions order by the Regulator must comply with it.

Product moratorium orders

225 Product moratorium order

(1) The Regulator may make a product moratorium order for a therapeutic product if they—

(a) suspect that the product does either or both of the following:

(i) directly or indirectly exposes any individual to a risk of death, serious injury, or serious illness:

(ii) creates or increases a significant risk to personal health or public health; and

(b) are satisfied on reasonable grounds that it is necessary or desirable to impose a moratorium on the product, having regard to—

(i) the likely benefits of, and risks associated with, the product; and

(ii) the purpose of a product moratorium order in subsection (3).

(2) A **product moratorium order** is an order that prohibits any person from doing either or both of the following with a specified therapeutic product:

(a) carrying on 1 or more supply chain activities:

(b) advertising it or recommending its use.

(3) The purpose of a product moratorium order is to temporarily restrict the availability of the product while the Regulator—

(a) evaluates,—

(i) in the case of a medicine, its safety, quality, and efficacy; or

(ii) in the case of a medical device, its safety, quality, and performance; or

(iii) in the case of an NHP, its safety and quality; and

(b) takes any other action the Regulator thinks is appropriate to manage the likely risks associated with the product.

(4) The Regulator must serve a copy of the order on the product's sponsor.

(5) A product moratorium order—

(a) takes effect on the day after the date on which it is published on the Regulator's website or on any later date set out in it; and

(b) expires on the date set out in it (which must not be more than 12 months after it is made), unless it is revoked before then.

226 Compliance with product moratorium order

A person must comply with a product moratorium order if—

(a) it has been served on them by the Regulator; or

(b) they are a person in the supply chain and they—

(i) know that the order is in force; or

(ii) are reckless as to whether the order is in force; or

(c) they are not a person in the supply chain and they know that the order is in force.

Prohibited product order

227 Prohibited product order

(1) The Regulator may make a prohibited product order if satisfied on reasonable grounds that a person is in possession of a prohibited product.

(2) A **prohibited product order** is an order directing a person to—

(a) destroy the product; or

(b) give it to the Regulator.

(3) The Regulator may seize any prohibited product that is given to them.

(4) This section applies to a product that has been misrepresented to be a therapeutic product as if it were a prohibited product (*see also* section 205(3)).

Guidance note

Section 247 provides for the destruction of seized things.

228 Compliance with prohibited product order

A person who has been served with a prohibited product order by the Regulator must comply with it.

Oversupplied persons

229 Regulator's powers in relation to oversupplied persons

(1) If the Regulator is satisfied on reasonable grounds 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 individual under section 230:

(b) make a statement about the individual under section 232.

(2) An individual is an **oversupplied person** if—

(a) the individual—

(i) is addicted or habituated to a prescription medicine or pharmacist medicine; or

(ii) has, over a period of time, obtained, or obtained prescriptions for, a quantity of a prescription medicine or pharmacist medicine that is greater than is reasonably necessary for their own therapeutic use; and

(b) they 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 230 and 232 may be exercised only—

(a) by the Regulator personally 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 (which delegation must be made in writing).

230 Medicine access limitation order

(1) The Regulator may make a medicine access limitation order in relation to an individual if satisfied on reasonable grounds that the individual is an oversupplied person (but *see* section 229(3)).

(2) A **medicine access limitation order** is an order relating to a specific individual that—

(a) prohibits any person from doing either or both of the following:

(i) supplying any specified prescription medicines or pharmacist medicines to the individual:

(ii) prescribing any of those medicines for the individual; and

(b) prohibits the individual from obtaining, or obtaining a prescription for, any of those medicines or attempting to do so.

(3) However, a medicine access limitation order may permit the supply or prescribing of specified quantities of a specified medicine to or for the individual by a specified person in specified circumstances.

(4) A medicine access limitation order must set out the date on which it expires, which must not be more than 3 years after it is made.

(5) The Regulator must review a medicine access limitation order at least once every 12 months to determine—

(a) whether the individual is still an oversupplied person; and

(b) whether the terms of the order are still appropriate.

(6) If not satisfied of either of those matters, the Regulator must revoke or amend the order accordingly.

231 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) it has been served on them by the Regulator; or

(b) they know that, or are reckless as to whether, the order is in force.

(2) An individual who is the subject of a medicine access limitation order and has been served with the order by the Regulator must comply with it.

232 Statement about oversupplied person

(1) If the Regulator is satisfied on reasonable grounds that an individual is an oversupplied person, they may (subject to section 229(3)) make a statement about the individual for the purpose of doing either or both of the following:

(a) limiting the supply of prescription medicines or pharmacist 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 they think is reasonably necessary for those purposes.

(3) The Regulator may disclose the statement to 1 or more notifiable persons if satisfied on reasonable grounds that—

(a) the disclosure is reasonably necessary for the purposes set out in subsection (1); and

(b) the notifiable person to whom it is disclosed will not disclose it to anyone else unless the disclosure is necessary for the purposes set out in subsection (1).

(4) The Regulator may arrange for the statement to be recorded in the individual's records on the National Health Index if satisfied on reasonable grounds that the record will not be accessible by anyone other than the individual, notifiable persons, and persons to whom it could be disclosed under subsection (3)(b).

(5) Except as permitted by subsections (3) and (4), the Regulator must not disclose the statement without the consent of the individual.

(6) If the statement is disclosed to a notifiable person, subsections (3) to (5) apply to that person as if they were the Regulator.

(7) The individual may make a complaint about the disclosure of the statement under Part 5 of the Privacy Act 2020 as if the definition of an interference with the privacy of an individual in section 69 of that Act included a breach of subsection (3), (4), or (5).

(8) No proceedings (whether civil or criminal), other than proceedings for judicial review or under the Privacy Act 2020, may be brought against the Regulator, the Crown, or any other person acting for or on behalf of the Regulator, in respect of a statement made under this section in good faith.

(9) In this section,—

disclose, in relation to a statement, includes disclosing any of the contents of the statement

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 allowed under this Act to supply by non-wholesale supply, prescribe, or administer, in the course of a business or undertaking, a medicine to which the statement relates:

(d) the chief executive of the Ministry:

(e) the chief executive of Health New Zealand:

(f) *[Repealed]*

(g) a certified provider of health care services of any kind (*see* section 26 of the Health and Disability Services (Safety) Act 2001):

(h) the manager of a treatment centre (as defined in section 4 of the Substance Addiction (Compulsory Assessment and Treatment) Act 2017):

(i) a prison manager (as defined in section 3 of the Corrections Act 2004):

(j) the Commissioner of Police:

(k) a practitioner regulatory body:

(l) the Health and Disability Commissioner.

Section 232(9)(f): repealed, on 30 June 2024, by section 43 of the Pae Ora (Disestablishment of Māori Health Authority) Amendment Act 2024 (2024 No 5).

All regulatory orders

233 Content of regulatory orders

(1) A regulatory order may do any of the following:

(a) specify how, and by when, anything required by the order must be done:

(b) require something to be done to the satisfaction of the Regulator:

(c) require a person to give the Regulator evidence that they have complied with the order.

(2) A regulatory order may (subject to the provision under which it is made) do either or both of the following:

(a) make provision for things either unconditionally or subject to conditions:

(b) include any terms the Regulator thinks are 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's 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.

234 Opportunity to comment before making regulatory order

(1) The Regulator must not make a regulatory order unless they have given the affected persons an opportunity to comment.

(2) The **affected persons** are,—

(a) if it is a recall order, the product's sponsor:

(b) if it is 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) if it is an advertising remediation order,—

(i) the person who distributed the advertisement; and

(ii) if another person caused the distribution of the advertisement, that person:

(d) if it is a directions order, the persons it will apply to.

(3) However, this section does not apply to a medicine access limitation order, product moratorium order, or prohibited product order.

235 Regulatory orders to be publicly available

(1) The Regulator must make a regulatory order publicly available.

(2) However, a failure to do so does not affect the validity of the order.

(3) This section does not apply to a medicine access limitation order, which must not be made publicly available.

Guidance note

Public availability requirements are set out in section 388.

236 Regulatory order overrides licence, permit, or provision of subpart 3 of Part 3

(1) If a regulatory order prohibits a person from doing something, the order has effect even if the person is allowed by a licence, permit, or provision of subpart 3 of Part 3 to do it.

(2) If a regulatory order requires a person to do something, the order has effect, even if the person would otherwise be prohibited under this Act from doing it.

237 Variation of regulatory order

(1) The Regulator may vary a regulatory order—

(a) on application by—

(i) a person who must comply with the order; or

(ii) if the order (other than a medicine access limitation order) relates to a therapeutic product with a market authorisation, the product's sponsor; or

(b) on their own initiative.

(2) However, the Regulator must not vary an order so as to make it more onerous unless they have complied with section 234.

(3) A person who was served with the original order must comply with the order as varied only after being served with notice of the variation.

Guidance note

Decisions under this section are reviewable under subpart 6 of Part 9.

238 Revocation of regulatory order

(1) The Regulator may revoke a regulatory order—

(a) on application by—

(i) a person who must comply with the order; or

(ii) if the order (other than a medicine access limitation order) relates to a product with a market authorisation, the product's sponsor; or

(b) on their own initiative.

(2) The Regulator must—

(a) serve notice of the revocation on all persons who were served with the order; and

(b) take reasonable steps to ensure that other persons who were required to comply with the order are made aware of its revocation.

Guidance note

Decisions under this section are reviewable under subpart 6 of Part 9.

Subpart 4—Public safety announcements

239 Public safety announcements

(1) For the purpose of protecting, promoting, or improving personal health or public health, the Regulator may make a statement relating to any 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) The Regulator may include in the statement any information they think is appropriate.

(3) The Regulator must make the statement publicly available and may disseminate it in any other way they think is 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 on reasonable grounds 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, the Crown, or any other person acting for or on behalf of the Regulator, in respect of a statement made under this section in good faith.

(6) This section also applies to the chief executive of the Ministry if they make a statement of the kind referred to in subsection (1) in the course of exercising their powers under this Act (for example, in connection with making an emergency arrangements notice under section 119).

Subpart 5—Official statements for exports

240 Official statement for export of therapeutic product

(1) The Regulator may, on application, issue a statement (an **official statement**) for a therapeutic product that is to be exported.

(2) In an official statement, the Regulator may certify any of the following (as is applicable):

- (a) that the product has a market authorisation of a specified kind:
- (b) that the product meets the product standards or export standards (or both) that apply to it:
- (c) that any other criteria, standards, or requirements applying to the product under this Act are met or complied with:
- (d) that a named person is allowed to export the product:
- (e) that a specified process has been completed under this Act in respect of the product:
- (f) that the situation in New Zealand, in relation to any matter relating to the product, is as described in the statement.

(3) An application may be made by—

- (a) the sponsor of a therapeutic product with a market authorisation; or
- (b) the licensee or permit holder if their licence or permit allows them to export a therapeutic product.

(4) In deciding whether to issue an official statement, the Regulator must comply with any requirements in the regulations.

(5) An official statement—

(a) must contain any information required by the regulations; and

(b) may contain any other information the Regulator thinks is appropriate.

Guidance note

The procedural and administrative requirements in sections 379 to 386 apply to an application under this section.

Decisions under this section are reviewable under subpart 6 of Part 9.

Part 8
Enforcement

241 Application of Part to products without market authorisation and misrepresented products

(1) In relation to a therapeutic product that does not have a market authorisation, a reference in this Part to the product's **sponsor** is taken to refer to,—

(a) if the responsible manufacturer meets the criterion in section 124(1)(a) or 128(1)(a), that person; or

(b) if paragraph (a) does not apply but another manufacturer meets that criterion, that person; or

(c) if neither paragraph (a) nor (b) applies, the importer of the product.

(2) However,—

(a) if, as a result of subsection (1), the Regulator is required to do something in relation to a person referred to in subsection (1) (such as give them information); and

(b) after making reasonable efforts to do so, the Regulator is unable to identify or locate the person,—

the Regulator is not required to comply with that requirement.

(3) Subsection (1) does not apply to the references to a sponsor in sections 250, 269, 272, and 281.

(4) If a product is misrepresented to be a therapeutic product, this Part applies (with any necessary modifications) as if the product were a therapeutic product that did not have a market authorisation.

Guidance note

In relation to misrepresentation, *see* section 193.

Subpart 1—Investigative powers

242 Exercising powers for enforcement purposes

(1) Exercising a power for **enforcement purposes** means exercising the power for the purposes of enabling the Regulator to do any of the following:

(a) investigate non-compliance or suspected non-compliance with this Act:

(b) obtain evidential material in relation to contraventions, or suspected contraventions, of this Act:

(c) perform their functions and exercise their powers under this Part:

(d) otherwise enforce compliance with this Act.

(2) If—

(a) a power conferred by this subpart is exercised in relation to a civil penalty contravention under section 272; and

(b) under this subpart, a provision of the Search and Surveillance Act 2012 applies to the exercise of that power,—

that provision of the Search and Surveillance Act 2012 applies as if any reference in it to an offence were a reference to the civil penalty contravention and with any other necessary modifications.

243 Entry and search for enforcement purposes

(1) The Regulator may, for enforcement purposes, authorise an inspector to enter and search a specific place if the Regulator is satisfied that there are reasonable grounds to suspect that—

(a) a person has contravened, is contravening, or will contravene a provision of this Act; and

(b) the search will find evidential material.

(2) The inspector may enter and search the place—

(a) with the consent of the occupier or person in charge of the place; or

(b) under a search warrant issued under section 244.

(3) Subpart 2 of Part 3 and Part 4 (except sections 118 and 119) of the Search and Surveillance Act 2012 apply, with any necessary modifications, to a search under this section.

(4) The power under subsection (2) to enter and search a place includes a power for the inspector to exercise their powers under subpart 2 of Part 7 of this Act for the purposes of the search, and the provisions in that subpart apply with any necessary modifications.

(5) This section does not limit section 245.

244 Search warrants

(1) An issuing officer may, on application by an inspector, issue a search warrant in relation to a place if satisfied that there are reasonable grounds to suspect that—

(a) a person has contravened, is contravening, or will contravene a provision of this Act; and

(b) the search will find evidential material.

(2) The inspector may make an application only if authorised under section 243(1) to enter and search the place.

(3) The inspector must make the application in accordance with subpart 3 of Part 4 of the Search and Surveillance Act 2012.

(4) In this section, **issuing officer** has the same meaning as in section 3 of the Search and Surveillance Act 2012.

245 Continuation of regulatory powers for enforcement purposes

If an inspector is exercising a power under subpart 2 of Part 7 for regulatory purposes and finds evidential material in relation to a contravention or suspected contravention of a provision of this Act,—

(a) they may remain at the place and continue exercising that power for enforcement purposes; and

(b) this subpart (including the provisions of the Search and Surveillance Act 2012 applied by section 243) applies as if they were acting under a search warrant.

246 Power to require person to give name and address

(1) An inspector may require a person to give the inspector their name and residential address if the inspector—

(a) finds the person contravening a provision of this Act; or

(b) reasonably suspects that the person has done so.

(2) The inspector must tell the person—

(a) why they are required to provide their name and address; and

(b) that not doing so is an offence unless they have a reasonable excuse for not doing so.

(3) If the inspector reasonably suspects that the name or address given by the person is false, they may require the person to provide evidence that it is correct.

Guidance note

A person who is required by an inspector to give their name and address or supporting evidence must do so (*see* section 203).

Seized things

247 Destruction of seized things

(1) Subsection (2) applies if—

(a) something is seized—

(i) by the Regulator or an inspector under this Act (including in the exercise of a power under the Search and Surveillance Act 2012 for the purposes of this Act); or

(ii) by Customs under section 242(1)(b)(vii) of the Customs and Excise Act 2018; and

(b) the Regulator is satisfied on reasonable grounds that any of the following apply to the seized thing:

(i) in the case of a medicine or an API, its safety, quality, or efficacy may not be acceptable:

(ii) in the case of a medical device, its safety, quality, or performance may not be acceptable:

(iii) in the case of an NHP, its safety or quality may not be acceptable:

(iv) it is a prohibited product or is subject to a product moratorium order:

(v) it is a product that was misrepresented to be a therapeutic product:

(vi) it has been used in the commission of an offence or a civil penalty contravention under this Act:

(vii) if it is released to the person from whom it was seized or to another person who is entitled to it, it is likely to be used in the commission of an offence or a civil penalty contravention under this Act:

(viii) a requirement given under section 248 in relation to it has not been complied with.

(2) Section 160 of the Search and Surveillance Act 2012 (disposal of unlawful items) applies as if—

(a) possession of the seized thing by the person from whom it was seized, or another person who is entitled to it, is unlawful under a New Zealand law; and

(b) the Regulator were the person who seized it.

248 Removal from New Zealand of seized things that are imported

(1) This section applies to something—

(a) that is imported into New Zealand and is seized by the Regulator under this Act (including in the exercise of a power under the Search and Surveillance Act 2012 for the purposes of this Act); or

(b) that is seized by Customs under section 242(1)(b)(vii) of the Customs and Excise Act 2018.

(2) The Regulator may, by written notice served on the importer, require them to return the thing to its place of origin or otherwise remove it from New Zealand within the time specified in the notice (which must allow the person a reasonable time to comply).

(3) If the product is not removed from New Zealand within that time, the Regulator may—

(a) return the thing to its place of origin or otherwise remove it from New Zealand; or

(b) deal with it in accordance with section 247.

249 Recovery of seizure-related costs

(1) If the Regulator or Customs incurs seizure-related costs in relation to a seized thing, the Regulator may recover the costs from any of the following:

(a) any person who is convicted of an offence or has a civil penalty order made against them in relation to the seized thing:

(b) its owner:

(c) the person from whom it was seized:

(d) if section 248 applies to it, the importer.

(2) The costs may be recovered by the Regulator in a court of competent jurisdiction as a debt due to the Regulator (*see also* section 333).

(3) In this section, **seizure-related costs** 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 to its place of origin, removing it from New Zealand, or destroying it).

Subpart 2—Offences involving knowledge, recklessness, or intent

250 Significant risk to personal health or public health—level 1 penalty

(1) A person commits an offence if—

(a) they contravene a provision listed in subsection (3); and

(b) in doing so, they create or increase a significant risk to personal health or public health; and

(c) they know that, or are reckless as to whether, their conduct has that effect.

(2) They are liable on conviction,—

(a) if they are an individual, to imprisonment for a term not exceeding 5 years or to a fine not exceeding $200,000, or both; or

(b) otherwise, to a fine not exceeding $1 million.

(3) The provisions are:

(a) section 68 (market authorisation required to import, supply, or export):

(b) section 69 (sponsor's consent required to import product with standard authorisation or provisional authorisation):

(c) section 70 (controlled activity prohibited unless allowed by licence, permit, or subpart 3):

(d) section 71 (non-wholesale supply of prescription medicine: prescription required):

(e) section 72 (administering NHP by injection or parenteral infusion):

(f) section 73 (person in supply chain must comply with rules):

(g) section 74 (person in supply chain must comply with qualification, training, and competency requirements):

(h) section 75 (prohibited products):

(i) section 142 (sponsor must ensure compliance with market authorisation):

(j) section 143 (sponsor must ensure product meets product standards):

(k) section 144 (sponsor must ensure product meets export standards):

(l) section 146 (sponsor must comply with rules):

(m) section 147 (sponsor must notify Regulator of certain minor changes):

(n) section 185 (licensee and permit holder must comply with qualification, training, and competency requirements):

(o) section 191 (supply chain activity with tampered-with products):

(p) section 199 (agreeing or offering to carry on supply chain activity unlawfully):

(q) section 218 (compliance with recall order):

(r) section 228 (compliance with prohibited product order).

251 Significant risk to personal health or public health—level 2 penalty

(1) A person commits an offence if—

(a) they contravene a provision listed in subsection (3); and

(b) in doing so, they create or increase a significant risk to personal health or public health; and

(c) they know that, or are reckless as to whether, their conduct has that effect.

(2) They are liable on conviction,—

(a) if they are an individual, to a fine not exceeding $100,000; or

(b) otherwise, to a fine not exceeding $500,000.

(3) The provisions are:

(a) section 182 (licensee must ensure responsible person has authority and resources):

(b) section 183 (licensee or permit holder must ensure health practitioner or veterinarian has authority and resources):

(c) section 188 (responsible person must comply with rules):

(d) section 189 (pharmacy licensee must ensure pharmacy activities are carried on by persons allowed to do so):

(e) section 222 (compliance with advertising remediation order).

252 Offence for inducing health practitioner or veterinarian to act unprofessionally

(1) A person commits an offence if they contravene section 184.

(2) They are liable on conviction,—

(a) if they are an individual, to a fine not exceeding $100,000; or

(b) otherwise, to a fine not exceeding $500,000.

253 Offences for tampering with therapeutic product

(1) A person commits an offence if—

(a) they contravene section 190(1); and

(b) in doing so, they create or increase a significant risk to personal health or public health; and

(c) they know that, or are reckless as to whether, their conduct has that effect.

(2) A person commits an offence if—

(a) they contravene section 190(2); and

(b) either—

(i) they do so with the intention of doing any of the following:

(A) causing public alarm in New Zealand:

(B) causing direct economic loss to anyone involved in the supply of the product:

(C) causing, or creating a risk of, harm to public health; or

(ii) in doing so, they are reckless as to whether their conduct will have any of those effects.

(3) A person who commits an offence against subsection (1) or (2) is liable on conviction,—

(a) if they are an individual, to imprisonment for a term not exceeding 5 years or to a fine not exceeding $200,000, or both; or

(b) otherwise, to a fine not exceeding $1 million.

254 Offences for misrepresentation about therapeutic product

(1) A person commits an offence if—

(a) they contravene section 193; and

(b) they know that the representation is not true.

(2) They are liable on conviction,—

(a) if they are an individual, to imprisonment for a term not exceeding 1 year or to a fine not exceeding $100,000, or both; or

(b) otherwise, to a fine not exceeding $500,000.

(3) A person commits an offence if—

(a) they contravene section 193; and

(b) they are reckless as to whether the representation is true.

(4) They are liable on conviction,—

(a) if they are an individual, to a fine not exceeding $50,000; or

(b) otherwise, to a fine not exceeding $250,000.

255 Offences for holding out misrepresentation

(1) A person commits an offence if—

(a) they contravene section 194; and

(b) they know that the representation is not true; and

(c) they make it with intent to—

(i) deceive a person (including the Regulator); or

(ii) wrongfully obtain a commercial gain or avoid a commercial loss; or

(iii) wrongfully obtain a material benefit or avoid a material detriment.

(2) They are liable on conviction,—

(a) if they are an individual, to imprisonment for a term not exceeding 5 years or to a fine not exceeding $200,000, or both; or

(b) otherwise, to a fine not exceeding $1 million.

(3) A person commits an offence if—

(a) they contravene section 194; and

(b) they know that the representation is not true; and

(c) they make it with intent to undermine the purposes of this Act.

(4) They are liable on conviction,—

(a) if they are an individual, to a fine not exceeding $100,000; or

(b) otherwise, to a fine not exceeding $500,000.

256 Offence for impermissible health benefit claims about NHPs

(1) A person commits an offence if—

(a) they contravene section 195; and

(b) either—

(i) they know that the claim is not a permitted health benefit claim; or

(ii) they are reckless as to whether the claim is a permitted health benefit claim.

(2) They are liable on conviction,—

(a) if they are an individual, to imprisonment for a term not exceeding 1 year or to a fine not exceeding $100,000, or both; or

(b) otherwise, to a fine not exceeding $500,000.

257 Offence for unlawful advertising

(1) A person commits an offence if—

(a) they contravene section 197; and

(b) they know that, or are reckless as to whether, 1 or more of the following are the case:

(i) the product does not have a standard authorisation or provisional authorisation or an export authorisation (as the case requires):

(ii) the advertisement does not meet the advertisement requirements:

(iii) the advertisement is distributed in a way that does not comply with the requirements about distribution referred to in section 197(1)(c):

(iv) in the case of a contravention of section 197(6), the product is a prohibited product.

(2) They are liable on conviction,—

(a) if they are an individual, to imprisonment for a term not exceeding 1 year or to a fine not exceeding $100,000, or both; or

(b) otherwise, to a fine not exceeding $500,000.

258 Offence for misleading information in records

(1) A person commits an offence if—

(a) they contravene section 201; and

(b) they know that, or are reckless as to whether, the information is misleading information.

(2) They are liable on conviction,—

(a) if they are an individual, to imprisonment for a term not exceeding 5 years or to a fine not exceeding $200,000, or both; or

(b) otherwise, to a fine not exceeding $1 million.

259 Offences for giving misleading information to Regulator or inspector

(1) A person commits an offence if—

(a) they contravene section 202; and

(b) they engage in the conduct constituting the contravention with intent to—

(i) wrongfully obtain a commercial gain or avoid a commercial loss; or

(ii) wrongfully obtain a material benefit or avoid a material detriment; or

(iii) undermine the purposes of this Act.

(2) They are liable on conviction,—

(a) if they are an individual, to imprisonment for a term not exceeding 5 years or to a fine not exceeding $200,000, or both; or

(b) otherwise, to a fine not exceeding $1 million.

(3) A person commits an offence if—

(a) they contravene section 202; and

(b) they know that the information is misleading.

(4) They are liable on conviction,—

(a) if they are an individual, to a fine not exceeding $100,000; or

(b) otherwise, to a fine not exceeding $500,000.

(5) A person commits an offence if—

(a) they contravene section 202; and

(b) they are reckless as to whether the information is misleading.

(6) They are liable on conviction,—

(a) if they are an individual, to a fine not exceeding $50,000; or

(b) otherwise, to a fine not exceeding $250,000.

260 Offences for non-compliance with regulatory or investigative requirement

(1) A person commits an offence if—

(a) they contravene section 203 by not doing something they are required to do; and

(b) they know that they are required to do the thing.

(2) They are liable on conviction,—

(a) if they are an individual, to a fine not exceeding $100,000; or

(b) otherwise, to a fine not exceeding $500,000.

(3) A person commits an offence if—

(a) they contravene section 203 by not doing something they are required to do; and

(b) they are reckless as to whether they are required to do the thing.

(4) They are liable on conviction,—

(a) if they are an individual, to a fine not exceeding $50,000; or

(b) otherwise, to a fine not exceeding $250,000.

261 Offences for obstructing Regulator or inspector

(1) A person commits an offence if—

(a) they contravene section 204; and

(b) they do so with intent to obstruct the Regulator or inspector.

(2) They are liable on conviction,—

(a) if they are an individual, to a fine not exceeding $100,000; or

(b) otherwise, to a fine not exceeding $500,000.

(3) A person commits an offence if—

(a) they contravene section 204; and

(b) they are reckless as to whether they will obstruct the Regulator or inspector.

(4) They are liable on conviction,—

(a) if they are an individual, to a fine not exceeding $50,000; or

(b) otherwise, to a fine not exceeding $250,000.

262 Offence for non-compliance with premises restriction order

(1) A person commits an offence if—

(a) they contravene section 220; and

(b) in doing so, they directly or indirectly expose any individual to a risk of death, serious injury, or serious illness; and

(c) they know that, or are reckless as to whether, their conduct has that effect.

(2) They are liable on conviction,—

(a) if they are an individual, to imprisonment for a term not exceeding 5 years or to a fine not exceeding $200,000, or both; or

(b) otherwise, to a fine not exceeding $1 million.

263 Offence for non-compliance with directions order

(1) A person commits an offence if—

(a) they contravene section 224; and

(b) in doing so, they directly or indirectly expose any individual to a risk of death, serious injury, or serious illness; and

(c) they know that, or are reckless as to whether, their conduct has that effect.

(2) They are liable on conviction,—

(a) if they are an individual, to a fine not exceeding $100,000; or

(b) otherwise, to a fine not exceeding $500,000.

264 Offence for non-compliance with product moratorium order

(1) A person commits an offence if—

(a) they contravene section 226; and

(b) in doing so, they do either or both of the following:

(i) directly or indirectly expose any individual to a risk of death, serious injury, or serious illness:

(ii) create or increase a significant risk to personal health or public health; and

(c) they know that, or are reckless as to whether, their conduct has that effect.

(2) They are liable on conviction,—

(a) if they are an individual, to imprisonment for a term not exceeding 5 years or to a fine not exceeding $200,000, or both; or

(b) otherwise, to a fine not exceeding $1 million.

265 Offence for non-compliance with medicine access limitation order

(1) A person commits an offence if—

(a) they contravene section 231(1); and

(b) in doing so, they directly or indirectly create or increase a significant risk to the health of the individual who is the subject of the order; and

(c) they know that, or are reckless as to whether, their conduct has that effect.

(2) They are liable on conviction,—

(a) if they are an individual, to imprisonment for a term not exceeding 5 years or to a fine not exceeding $200,000, or both; or

(b) otherwise, to a fine not exceeding $1 million.

266 Offences for non-compliance with enforceable undertaking

(1) A person commits an offence if—

(a) they contravene section 299; and

(b) in doing so, they create or increase a significant risk to personal health or public health; and

(c) they know that, or are reckless as to whether, their conduct has that effect.

(2) They are liable on conviction,—

(a) if they are an individual, to imprisonment for a term not exceeding 5 years or to a fine not exceeding $200,000, or both; or

(b) otherwise, to a fine not exceeding $1 million.

(3) A person commits an offence if—

(a) they contravene section 299; and

(b) they know that their conduct contravenes the undertaking.

(4) They are liable on conviction,—

(a) if they are an individual, to a fine not exceeding $100,000; or

(b) otherwise, to a fine not exceeding $500,000.

(5) A person commits an offence if—

(a) they contravene section 299; and

(b) they are reckless as to whether their conduct contravenes the undertaking.

(6) They are liable on conviction,—

(a) if they are an individual, to a fine not exceeding $50,000; or

(b) otherwise, to a fine not exceeding $250,000.

267 Offence for unlawful disclosure of information

(1) A person commits an offence if—

(a) they contravene section 352; and

(b) they disclose the information—

(i) knowing that, or reckless as to whether, doing so is unlawful; or

(ii) otherwise in bad faith.

(2) They are liable on conviction,—

(a) if they are an individual, to a fine not exceeding $100,000; or

(b) otherwise, to a fine not exceeding $500,000.

Subpart 3—Offences not involving knowledge or recklessness

268 Strict liability offence—level 1 penalty

(1) A person commits an offence if they contravene a provision listed in subsection (3).

(2) They are liable on conviction,—

(a) if they are an individual, to a fine not exceeding $100,000; or

(b) otherwise, to a fine not exceeding $500,000.

(3) The provisions are—

(a) section 187 (protection of responsible person from retaliation):

(b) section 198 (improper inducement to health practitioner or veterinarian).

269 Strict liability offence—level 2 penalty

(1) A person commits an offence if they contravene a provision listed in subsection (3).

(2) They are liable on conviction,—

(a) if they are an individual, to a fine not exceeding $50,000; or

(b) otherwise, to a fine not exceeding $250,000.

(3) The provisions are—

(a) section 68 (market authorisation required to import, supply, or export):

(b) section 69 (sponsor's consent required to import product with standard authorisation or provisional authorisation):

(c) section 70 (controlled activity prohibited unless allowed by licence, permit, or subpart 3):

(d) section 71 (non-wholesale supply of prescription medicine: prescription required):

(e) section 72 (administering NHP by injection or parenteral infusion):

(f) section 73 (person in supply chain must comply with rules):

(g) section 74 (person in supply chain must comply with qualification, training, and competency requirements):

(h) section 75 (prohibited products):

(i) section 142 (sponsor must ensure compliance with market authorisation):

(j) section 143 (sponsor must ensure product meets product standards):

(k) section 144 (sponsor must ensure product meets export standards):

(l) section 145 (sponsor must have surveillance and response system):

(m) section 146 (sponsor must comply with rules):

(n) section 147 (sponsor must notify Regulator of certain minor changes):

(o) section 185 (licensee and permit holder must comply with qualification, training, and competency requirements):

(p) section 190 (tampering with therapeutic product):

(q) section 191 (supply chain activity with tampered-with products):

(r) section 193 (misrepresentation about therapeutic product):

(s) section 195 (impermissible health benefit claims about NHPs):

(t) section 197 (advertising):

(u) section 199 (agreeing or offering to carry on supply chain activity unlawfully):

(v) section 201 (misleading information in records):

(w) section 202 (misleading information to Regulator or inspector).

270 Strict liability offence—level 3 penalty

(1) A person commits an offence if they contravene a provision listed in subsection (3).

(2) They are liable on conviction,—

(a) if they are an individual, to a fine not exceeding $30,000; or

(b) otherwise, to a fine not exceeding $170,000.

(3) The provisions are—

(a) section 182 (licensee must ensure responsible person has authority and resources):

(b) section 183 (licensee or permit holder must ensure health practitioner or veterinarian has authority and resources):

(c) section 188 (responsible person must comply with rules):

(d) section 189 (pharmacy licensee must ensure pharmacy activities are carried on by persons allowed to do so):

(e) section 200 (obtaining therapeutic product when supply is unlawful):

(f) section 203(1) (compliance with regulatory or investigative requirement):

(g) section 204 (obstructing Regulator or inspector):

(h) section 218 (compliance with recall order):

(i) section 220 (compliance with premises restriction order):

(j) section 222 (compliance with advertising remediation order):

(k) section 224 (compliance with directions order):

(l) section 226 (compliance with product moratorium order):

(m) section 228 (compliance with prohibited product order):

(n) section 231(1) (compliance with medicine access limitation order):

(o) section 299 (compliance with enforceable undertaking).

271 Proof of state of mind not required for strict liability offence

In proceedings against a person for an offence against section 268, 269, or 270, it is not necessary to prove that the person intended to commit the offence or had any other state of mind in relation to any element of the offence.

Subpart 4—Civil liability

Civil penalty contravention

272 Civil penalty contravention

(1) A person commits a civil penalty contravention if—

(a) they contravene a provision listed in subsection (3); and

(b) they do so—

(i) in the course of a business or undertaking; or

(ii) to make a commercial gain or avoid a commercial loss.

(2) They are liable to have a civil penalty order made against them.

(3) The provisions are—

(a) section 69 (sponsor's consent required to import product with standard authorisation or provisional authorisation):

(b) section 70 (controlled activity prohibited unless allowed by licence, permit, or subpart 3):

(c) section 73 (person in supply chain must comply with rules):

(d) section 74 (person in supply chain must comply with qualification, training, and competency requirements):

(e) section 142 (sponsor must ensure compliance with a market authorisation):

(f) section 143 (sponsor must ensure product meets product standards):

(g) section 144 (sponsor must ensure product meets export standards):

(h) section 145 (sponsor must have surveillance and response system):

(i) section 146 (sponsor must comply with rules):

(j) section 148 (sponsor of reportable product must notify Regulator of likely shortage):

(k) section 149 (sponsor of reportable product must notify decision to stop supplying product):

(l) section 182 (licensee must ensure responsible person has authority and resources):

(m) section 183 (licensee or permit holder must ensure health practitioner or veterinarian has authority and resources):

(n) section 184 (licensee, permit holder, or senior manager must not induce health practitioner or veterinarian to act unprofessionally):

(o) section 185 (licensee and permit holder must comply with qualification, training, and competency requirements):

(p) section 187 (protection of responsible person from retaliation):

(q) section 189 (pharmacy licensee must ensure pharmacy activities are carried on by persons allowed to do so):

(r) section 192 (notifying Regulator of suspicion of tampering):

(s) section 193 (misrepresentation about therapeutic product):

(t) section 194 (holding out misrepresentation):

(u) section 195 (impermissible health benefit claims about NHPs):

(v) section 197 (advertising):

(w) section 198 (improper inducement to health practitioner or veterinarian):

(x) section 199 (agreeing or offering to carry on supply chain activity unlawfully):

(y) section 200 (obtaining therapeutic product when supply is unlawful):

(z) section 201 (misleading information in records):

(za) section 202 (misleading information to Regulator or inspector):

(zb) section 218 (compliance with recall order):

(zc) section 222 (compliance with advertising remediation order):

(zd) section 226 (compliance with product moratorium order):

(ze) section 228 (compliance with prohibited product order).

273 Parties to civil penalty contravention

(1) A person **commits a civil penalty contravention** if the person—

(a) actually commits the civil penalty contravention; or

(b) is involved in the civil penalty contravention; or

(c) attempts to commit the civil penalty contravention.

(2) A person is **involved in** a civil penalty contravention if they—

(a) aid, abet, counsel, or procure the civil penalty contravention; or

(b) induce (by threats, promises, or otherwise) a person to commit the civil penalty contravention; or

(c) conspire with others to commit the civil penalty contravention.

(3) A person **attempts** to commit a civil penalty contravention if they—

(a) intend to commit, or to be involved in committing, the civil penalty contravention; and

(b) engage in conduct for the purpose of giving effect to that intention (even if, in the circumstances, giving effect to the intention was not possible).

(4) In relation to an attempt, a reference to the contravention includes a reference to the attempted contravention.

Civil penalty orders

274 Civil penalty order

(1) The High Court may, on application by the Regulator, make a civil penalty order against a person if satisfied that the person has committed a civil penalty contravention against section 272.

(2) A **civil penalty order** is an order that a person must pay to the Crown an amount specified in the order (a **civil penalty**).

275 Maximum civil penalty

The maximum civil penalty that a person can be ordered to pay is the greatest of whichever of the following are applicable:

(a) if the conduct constituting the contravention was a transaction, the consideration for the transaction:

(b) if the contravention resulted in the person making a commercial gain or avoiding a commercial loss, 3 times the amount of the gain made or loss avoided as a result of the contravention (if it can be ascertained):

(c) if the person is an individual, $250,000:

(d) if the person is not an individual, $2,000,000.

276 Considerations for determining amount of civil penalty

In determining the amount of a civil penalty to be imposed on a person, the court must take into account all relevant matters, which may include any of the following:

(a) the nature and extent of the contravention:

(b) the therapeutic product in relation to which the contravention happened:

(c) the nature and extent of—

(i) any gain made or loss avoided by the person because of the contravention:

(ii) any loss or damage suffered by any other person because of the contravention:

(d) the circumstances in which the contravention took place (including the person's state of mind):

(e) if the person is in the supply chain, their role in the supply chain:

(f) whether the person has previously been found by a court (in New Zealand or another country) in proceedings under an Act to have engaged in similar conduct.

Procedural matters for civil penalty proceedings

277 Rules of civil procedure and civil standard of proof apply

(1) Civil penalty proceedings are civil proceedings.

(2) The usual rules of court and rules of evidence and procedure for civil proceedings apply (including the standard of proof).

Guidance note

The Limitation Act 2010 provides a defence to a money claim (which includes a claim to have a civil penalty imposed) if the claim is filed after the time allowed under that Act.

278 Proof of state of mind not required

(1) In civil penalty proceedings against a person, their state of mind is relevant only—

(a) if the existence of a particular state of mind is an express element of the civil penalty contravention; and

(b) for the purposes of section 273 (if applicable).

(2) However, if a civil penalty order is made against the person, their state of mind may be a relevant consideration in determining the amount of the civil penalty to be imposed (*see* section 276).

279 Civil penalty payable to the Crown

(1) A civil penalty is payable to the Crown.

(2) However, the court making the civil penalty order may order all or part of it to be paid to the Regulator.

(3) A civil penalty is recoverable by the Regulator in a court of competent jurisdiction as a debt due to the Crown.

Subpart 5—Infringement offences

280 Interpretation

In this Act,—

infringement fee, in relation to an infringement offence, means the infringement fee for the offence set out in the regulations (*see* section 391)

infringement notice means a notice issued under section 283

infringement offence means—

(a) an offence against section 281; or

(b) an offence against a provision of the regulations that the regulations say is an infringement offence.

281 Infringement offence

(1) A person commits an infringement offence if they contravene any of the provisions listed in subsection (3).

(2) They are liable to—

(a) an infringement fee of the amount set out in the regulations; or

(b) a fine imposed by a court not exceeding the amount set out in the regulations.

(3) The provisions are—

(a) section 68 (market authorisation required to import, supply, or export):

(b) section 69 (sponsor's consent required to import product with standard authorisation or provisional authorisation):

(c) section 70 (controlled activity prohibited unless allowed by licence, permit, or subpart 3):

(d) section 73 (person in supply chain must comply with rules):

(e) section 74 (person in supply chain must comply with qualification, training, and competency requirements):

(f) section 142 (sponsor must ensure compliance with market authorisation):

(g) section 144 (sponsor must ensure product meets export standards):

(h) section 145 (sponsor must have surveillance and response system):

(i) section 146 (sponsor must comply with rules):

(j) section 147 (sponsor must notify Regulator of certain minor changes):

(k) section 148 (sponsor of reportable product must notify Regulator of likely shortage):

(l) section 149 (sponsor of reportable product must notify decision to stop supplying product):

(m) section 186 (responsible person must report non-compliance):

(n) section 188 (responsible person must comply with rules):

(o) section 189 (pharmacy licensee must ensure pharmacy activities are carried on by persons allowed to do so):

(p) section 192 (notifying Regulator of suspicion of tampering):

(q) section 193 (misrepresentation about therapeutic product):

(r) section 195 (impermissible health benefit claims about NHPs):

(s) section 197 (advertising):

(t) section 199 (agreeing or offering to carry on supply chain activity unlawfully):

(u) section 200 (obtaining therapeutic product when supply is unlawful):

(v) section 201 (misleading information in records):

(w) section 202 (misleading information to Regulator or inspector):

(x) section 203 (compliance with regulatory or investigative requirement):

(y) section 222 (compliance with advertising remediation order):

(z) section 226 (compliance with product moratorium order):

(za) section 228 (compliance with prohibited product order):

(zb) section 231(2) (compliance with medicine access limitation order).

282 Infringement notice or proceedings for infringement offences

(1) A person who is alleged to have committed an infringement offence may—

(a) be proceeded against by the filing of a charging document under section 14 of the Criminal Procedure Act 2011; or

(b) be issued with an infringement notice under section 283.

(2) Proceedings commenced in the way described in subsection (1)(a) do not require the leave of a District Court Judge or Registrar under section 21(1)(a) of the Summary Proceedings Act 1957.

Guidance note

See section 21 of the Summary Proceedings Act 1957 for the procedure that applies if an infringement notice is issued.

283 When infringement notice may be issued

An inspector may issue an infringement notice to a person if they believe on reasonable grounds that the person is committing, or has committed, an infringement offence.

284 Revocation of infringement notice before payment made

(1) The Regulator may revoke an infringement notice before—

(a) the infringement fee is paid; or

(b) an order for payment of a fine is made or deemed to be made by a court under section 21 of the Summary Proceedings Act 1957.

(2) The Regulator must take reasonable steps to ensure that the person to whom the notice was issued is made aware of the revocation of the notice.

(3) The revocation of an infringement notice before the infringement fee is paid is not a bar to any further action as described in section 282(1)(a) or (b) against the person to whom the notice was issued in respect of the same matter.

285 What infringement notice must contain

An infringement notice must be in the form set out in the regulations and must contain the following particulars:

(a) details of the alleged infringement offence that fairly inform a person of the time, place, and nature of the alleged offence:

(b) the amount of the infringement fee:

(c) the address of the Regulator:

(d) how the infringement fee may be paid:

(e) the time within which the infringement fee must be paid:

(f) a summary of the provisions of section 21(10) of the Summary Proceedings Act 1957:

(g) a statement that the person served with the notice has a right to request a hearing:

(h) a statement of what will happen if the person served with the notice neither pays the infringement fee nor requests a hearing:

(i) any other information required by the regulations.

286 How infringement notice may be served

(1) An infringement notice may be served on the person who the Regulator believes is committing or has committed the infringement offence by—

(a) delivering it to them or, if they refuse to accept it, bringing it to their notice; or

(b) leaving it for them at their last known place of residence with another person who appears to be of or over the age of 14 years; or

(c) leaving it for them at their place of business or work with another person; or

(d) sending it to them by prepaid post addressed to their last known place of residence or place of business or work; or

(e) sending it to an electronic address of the person in any case where they do not have a known place of residence or place of business or work in New Zealand.

(2) Unless the contrary is shown,—

(a) an infringement notice (or a copy of it) sent by prepaid post to a person under subsection (1) is to be treated as having been served on that person on the fifth working day after the date on which it was posted; and

(b) an infringement notice sent to a valid electronic address is to be treated as having been served at the time the electronic communication first entered an information system that is outside the control of the Regulator.

287 Reminder notices

A reminder notice must be in the form set out in the regulations and must contain the same, or substantially the same, particulars as the infringement notice.

288 Payment of infringement fees

All infringement fees paid for infringement offences must be paid into a Crown Bank Account.

Subpart 6—Interrelationship of civil penalty orders

289 Civil penalty contravention and offence

(1) This section applies if—

(a) a person's conduct constitutes a civil penalty contravention against section 272; and

(b) the same, or substantially the same, conduct constitutes an offence against—

(i) a provision of subpart 2 or 3; or

(ii) a provision of the regulations as referred to in section 391(1).

(2) If a prosecution is commenced against the person for the offence, proceedings cannot be commenced against them for the civil penalty contravention.

(3) If proceedings against the person for the civil penalty contravention have concluded, a prosecution cannot be commenced against them for the offence.

(4) If proceedings against the person for the civil penalty contravention have commenced but have not concluded,—

(a) a prosecution may be commenced against them for the offence; but

(b) if so, the proceedings for the civil penalty contravention must be withdrawn or dismissed.

290 Civil penalty contravention and infringement offence

(1) This section applies if—

(a) a person's conduct constitutes a civil penalty contravention against section 272; and

(b) the same, or substantially the same, conduct constitutes an infringement offence against another provision of this Act.

(2) If proceedings are commenced against the person for the civil penalty contravention,—

(a) proceedings cannot be commenced against them for the infringement offence by the filing of a charging document (*see* section 282(1)(a)); and

(b) an infringement notice cannot be issued to them for the infringement offence.

(3) If proceedings are commenced against the person for the infringement offence by the filing of a charging document, proceedings cannot be commenced against them for the civil penalty contravention.

(4) If an infringement notice is issued to the person for the infringement offence, proceedings cannot be commenced against them for the civil penalty contravention unless the infringement notice is revoked under section 284.

291 Two civil penalty contraventions

(1) This section applies if the same, or substantially the same, conduct of a person constitutes a civil penalty contravention against section 272 for a contravention of 2 or more provisions of this Act.

(2) Proceedings may be brought against the person in relation to 2 or more contraventions, but only 1 civil penalty order may be made against the person in relation to the conduct.

292 Civil penalty contravention and liability under other Acts

A person cannot, for the same or substantially the same conduct,—

(a) be ordered to pay a civil penalty under this Act; and

(b) be ordered to pay a civil penalty or be held criminally liable under any other Act.

293 Evidence given in civil penalty proceedings not admissible in criminal proceedings

(1) If a person gives information or produces documents in civil penalty proceedings against them, evidence of the information or documents is not admissible in later criminal proceedings against the person for an offence (against this or any other Act) that is constituted by the same, or substantially the same, conduct.

(2) However, this section does not apply to criminal proceedings relating to the falsity of the evidence given by the person in the civil penalty proceedings (such as a prosecution for perjury under the Crimes Act 1961).

Subpart 7—Enforceable undertakings

294 Regulator may accept undertaking

(1) The Regulator may, on application by a person, accept an undertaking given by the person in connection with an alleged contravention of a provision of this Act (the **alleged contravention**).

(2) Without limiting what an undertaking may relate to, an undertaking may include undertakings to do any of the following:

(a) pay compensation to any person:

(b) take action to avoid or mitigate any actual or likely adverse effects arising from the alleged contravention:

(c) take action to do either or both of the following:

(i) reduce the likelihood of future contraventions:

(ii) avoid or mitigate any likely adverse effects arising from future contraventions:

(d) pay to the Regulator the reasonable costs they have incurred doing either or both of the following:

(i) investigating the alleged contravention:

(ii) if the conduct constituting the alleged contravention directly or indirectly creates or increases a significant risk to personal health or public health, mitigating that risk.

(3) The Regulator must not accept an undertaking unless satisfied on reasonable grounds that—

(a) the person offering to give it is willing and able to comply with it; and

(b) accepting the undertaking is an appropriate way to address the alleged contravention.

(4) The Regulator must not accept an undertaking if—

(a) the person has previously contravened this Act; and

(b) the person was convicted of an offence or had a civil penalty order made against them in respect of the previous contravention; and

(c) the Regulator is satisfied on reasonable grounds that the conduct constituting the previous contravention is the same or substantially the same as that constituting the alleged contravention.

(5) Giving an undertaking is not an admission that the person giving it has committed the alleged contravention.

295 When undertaking becomes enforceable

(1) An undertaking takes effect and becomes enforceable when notice of the Regulator's decision to accept it is given to the person giving the undertaking or on any later date set out in it.

(2) An enforceable undertaking remains in force until—

(a) it expires or is complied with according to its terms; or

(b) it is withdrawn under section 297; or

(c) it is discharged by a court (*see* section 301).

296 Enforceable undertaking to be made publicly available

The Regulator must make the following publicly available:

(a) the enforceable 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 the variation:

(d) when the enforceable undertaking ceases to be in force, notice of—

(i) whether it expired or was complied with, withdrawn, or discharged; and

(ii) the date it ceased to be in force.

Guidance note

Public availability requirements are set out in section 388.

297 Withdrawal of enforceable undertaking

(1) A person who has given an enforceable undertaking may withdraw it but only with the written consent of the Regulator.

(2) If a request for the Regulator's consent is refused, the District Court may, on application by the person, make an order discharging the undertaking.

298 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.

(3) The Regulator must not accept an application to vary an enforceable undertaking unless satisfied on reasonable grounds that—

(a) the person is willing and able to comply with the varied undertaking; and

(b) the varied undertaking is an appropriate way to address the alleged contravention.

299 Compliance with enforceable undertaking

A person who has given an enforceable undertaking must comply with it.

Guidance note

Not complying with this section is an offence (*see* subparts 2 and 3).

300 No proceedings for alleged contravention if undertaking complied with

(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 them, and no infringement notice may be issued to them, for the alleged contravention—

(a) while the undertaking is in force; or

(b) at any later time, if they have complied with the undertaking.

(2) If the Regulator accepts an enforceable undertaking after proceedings for the alleged contravention have been commenced but before they are completed, the Regulator must discontinue the proceedings as soon as practicable.

301 Contravention of enforceable undertaking—court may discharge undertaking, etc

(1) The District Court may, on application by the Regulator, make an order under this section if satisfied on reasonable grounds that—

(a) a person who gave an enforceable undertaking has not complied with it; or

(b) the Regulator's acceptance of an enforceable undertaking was obtained by fraud or the use of misleading information, or in bad faith.

(2) An order under this section may do any 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 estimated costs of future monitoring).

(3) This section does not prevent proceedings being brought for the alleged contravention.

302 Limitation period for proceedings after enforceable undertaking contravened or ceases to be in force

(1) This section applies if—

(a) a person who has given an enforceable undertaking contravenes or withdraws it or a court discharges it; and

(b) the limitation period for commencing proceedings for the alleged contravention—

(i) expired on or before the relevant date; or

(ii) will expire not more than 6 months after the relevant date.

(2) Proceedings may be commenced against the person for the alleged contravention not more than 6 months after the relevant date (even if the limitation period that would otherwise apply has expired).

(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 or discharged.

Subpart 8—Enforcement against the Crown

303 Enforcement of Act against the Crown

This Act may be enforced against the Crown only in the manner provided in this subpart.

304 Offences under subpart 2 or 3

(1) An instrument of the Crown may be prosecuted for an offence against a provision of subpart 2 or 3 or the regulations, but only if—

(a) it is a Crown organisation; and

(b) the offence is a Crown-enforceable offence; and

(c) the proceedings are commenced—

(i) against the Crown organisation in its own name (and not against the Crown); and

(ii) in accordance with the Crown Organisations (Criminal Liability) Act 2002.

(2) In this section, a **Crown-enforceable offence** means—

(a) an offence against a provision of subpart 2 or 3 for a contravention of a provision listed in Schedule 2 for which there is a tick in the Crown-enforceable offence column; or

(b) an offence against a provision of the regulations as referred to in section 391(1) that the regulations say is a Crown-enforceable offence.

305 Infringement offences

(1) An instrument of the Crown may be issued with an infringement notice, but only if—

(a) it is a Crown organisation; and

(b) the offence is a Crown-enforceable infringement offence; and

(c) the notice is issued to the Crown organisation in its own name (and not to the Crown).

(2) An instrument of the Crown may be proceeded against as described in section 282(1)(a) in respect of an infringement offence, but only if—

(a) it is a Crown organisation; and

(b) the offence is a Crown-enforceable infringement offence; and

(c) the proceedings are commenced against the Crown organisation in its own name (and not against the Crown).

(3) In this section, a **Crown-enforceable infringement offence** means—

(a) an infringement offence against section 281 for a contravention of a provision listed in Schedule 2 for which there is a tick in the Crown-enforceable infringement offence column; or

(b) an infringement offence against a provision of the regulations that the regulations say is a Crown-enforceable infringement offence.

306 Civil penalty orders

(1) The Regulator cannot apply for (and a court cannot make) a civil penalty order against an instrument of the Crown.

(2) Subsection (1) does not prevent the Regulator applying for (or a court from making) a civil penalty order against a senior manager, worker, or agent of an instrument of the Crown for—

(a) the person's own conduct; or

(b) a contravention attributed to them under section 313.

(3) However, subsection (2) does not affect any defence or immunity from liability that the person may have under the Public Service Act 2020, the Crown Entities Act 2004, or any other legislation or rule of law.

307 Injunctions

Despite section 17(1)(a) of the Crown Proceedings Act 1950, an injunction may be granted or another order made under this Act against an instrument of the Crown, but only if—

(a) the instrument of the Crown is a Crown organisation; and

(b) the injunction or order is made against the Crown organisation in its own name (and not the Crown).

308 Enforceable undertakings

The Regulator may, under section 294, accept an enforceable undertaking from an instrument of the Crown, but only if—

(a) the instrument of the Crown is a Crown organisation; and

(b) the undertaking is made by the Crown organisation in its own name (and not the Crown).

309 Crown organisation as sponsor, licensee, or permit holder

(1) If a Crown organisation is a sponsor, licensee, or permit holder, the Regulator may, in relation to the Crown organisation, perform or exercise all of the functions and powers under this Act that the Regulator may perform or exercise in relation to any other sponsor, licensee, or permit holder.

(2) However, subsection (1) is subject to this subpart.

310 Recovery of unpaid amounts

(1) A provision of this Act that provides for the Regulator to recover an unpaid amount in a court of competent jurisdiction as a debt due to the Regulator does not apply to an amount payable by the Crown or a Crown organisation.

(2) However, subsection (1) does not affect—

(a) the Crown's or Crown organisation's obligation to pay the amount; and

(b) any other consequences that might result from the non-payment.

Example

An example of a consequence that might result from non-payment is the Regulator cancelling a market authorisation under which a Crown organisation is the sponsor for non-payment of a levy that is payable by sponsors.

Subpart 9—Attribution of liability

311 Conduct of senior managers, workers, and agents attributed to employer, etc

(1) This section applies 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.

(2) If this section applies,—

(a) person B is taken to have also engaged in the conduct; and

(b) if the conduct contravenes a provision of this Act, person B is taken to have also contravened the provision.

(3) Proceedings may be taken against person B in reliance on subsection (2) whether or not proceedings are taken against person A.

(4) In proceedings in reliance on subsection (2), it is a defence if person B—

(a) did not know, and could not reasonably be expected to have known, of the contravention; or

(b) took all reasonable steps to ensure that the conduct constituting the contravention did not occur.

312 State of mind of senior managers, workers, and agents attributed to employer, etc

(1) This section applies to an offence if—

(a) it is an offence against—

(i) a provision of subpart 2; or

(ii) a provision of the regulations as referred to in section 391(1); and

(b) it is an element of the offence that the person engaging in the conduct constituting the offence had a particular state of mind.

(2) In a prosecution of a person (**person A**) who is not an individual for the offence, 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.

313 Contravention of body corporate attributed to senior managers

(1) If a person (**person A**) who is not an individual contravenes a provision of this Act, another person (**person B**) who was a senior manager of person A when the contravention happened is taken to have also contravened the provision.

(2) Proceedings may be taken against person B in reliance on subsection (1) whether or not proceedings are taken against person A.

(3) In proceedings 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; or

(b) took all reasonable steps to ensure that the conduct constituting the contravention did not occur.

Subpart 10—Defences

314 Proceedings in which defences apply

(1) The defences in this subpart apply—

(a) in a prosecution of a person for an offence against—

(i) a provision of subpart 2 or 3; or

(ii) a provision of the regulations as referred to in section 391(1); and

(b) in proceedings against a person for a civil penalty contravention against section 272; and

(c) in proceedings against a person for an infringement offence in accordance with section 21 of the Summary Proceedings Act 1957.

(2) However, sections 318 and 319 only apply in proceedings for a contravention of section 193 or 197 respectively.

(3) In proceedings against a person in reliance on section 311 or 313 (person B in that section), person B has a defence under a provision of this subpart only if person A in section 311 or 313 would have a defence under that provision.

Guidance note

Sections 311 and 313 contain separate defences for person B.

315 All reasonable steps

In proceedings to which this subpart applies, it is a defence if the defendant took all reasonable steps—

(a) to ensure that the conduct constituting the contravention did not occur; and

(b) to mitigate any effect that conduct had in creating or increasing a significant risk to personal health or public health.

316 Reliance on information from another person

(1) In proceedings to which this subpart applies, it is a defence if—

(a) the contravention was due to the defendant's reliance on information given to them by another person; and

(b) in the circumstances, it was reasonable for the defendant to rely on that information.

(2) The defendant cannot rely on this defence unless—

(a) they notify the prosecutor or informant of the identity of the other person at least 7 days before the date on which the hearing of the proceedings is to commence; or

(b) the court gives them leave to rely on the defence without complying with paragraph (a).

317 Preventing death or very serious injury or illness

In proceedings to which this subpart applies, it is a defence if—

(a) the conduct constituting the contravention was necessary to prevent the death or very serious injury or illness of any individual; and

(b) the conduct was reasonable in the circumstances; and

(c) the defendant took all reasonable steps to mitigate any effect that the conduct had in creating or increasing a significant risk to personal health or public health.

318 Defences relating to misrepresentation about therapeutic product

(1) In proceedings for a contravention of section 193, other than a prosecution under section 254, it is a defence if—

(a) the defendant engaged in the conduct constituting the contravention in good faith for the purpose of any of the following:

(i) reporting of news or a matter of public concern:

(ii) research, study, or education:

(iii) criticism or review of a therapeutic product or information about a therapeutic product:

(iv) fundraising to enable the acquisition of a specified therapeutic product by or for a specified individual or individuals:

(v) advocating for a change to Government policy about therapeutic products (including about public funding for therapeutic products (either generally or specifically)); and

(b) it was reasonable in all the circumstances for the defendant to have believed the representation to be true.

(2) In proceedings for a contravention of section 193, it is a defence if the defendant made the representation in circumstances in which a reasonable person would not have believed that the representation was true.

319 Defence relating to advertising

In proceedings for a contravention of section 197, it is a defence if—

(a) the defendant engaged in the conduct constituting the contravention in good faith for the purpose of any of the following:

(i) reporting of news or a matter of public concern:

(ii) research, study, or education:

(iii) criticism or review of a therapeutic product or information about a therapeutic product:

(iv) fundraising to enable the acquisition of a specified therapeutic product by or for a specified individual or individuals:

(v) advocating for a change to Government policy about therapeutic products (including about public funding for therapeutic products (either generally or specifically)); and

(b) engaging in that conduct for that purpose was reasonable in all the circumstances.

Subpart 11—Evidentiary matters

320 Proof of risk to particular individual not required

(1) This section applies to an offence if one of the elements of the offence is that a person knows that, or is reckless as to whether, their conduct directly or indirectly—

(a) creates or increases a significant risk to personal health or public health; or

(b) exposes any individual to a risk of death, serious injury, or serious illness.

(2) In a prosecution of a person for the offence, it is not necessary to prove that the conduct—

(a) created or increased a significant risk to any specific individual; or

(b) exposed any specific individual to a risk of death or serious injury or serious illness.

321 Proof of knowledge of class of medicine not required

In a prosecution of a person for an offence against section 250 for a contravention of section 71 (non-wholesale supply of prescription medicine: prescription required), it is not necessary to prove that the person knew that the medicine was a prescription medicine.

322 Proof of unprofessional conduct not required

In proceedings against a person for a contravention of—

(a) section 183 (licensee or permit holder must ensure health practitioner or veterinarian has authority and resources); or

(b) section 184 (licensee, permit holder, or senior manager must not induce health practitioner or veterinarian to act unprofessionally),—

it is not necessary to prove that a health practitioner or veterinarian did act unprofessionally.

323 Proof of favourable clinical decision not required

In proceedings against a person for a contravention of section 198(1) (improper inducement to health practitioner or veterinarian), it is not necessary to prove that a health practitioner or veterinarian was induced to make, or has made, a favourable clinical decision about the product.

Regulatory order is sufficient evidence

324 Evidence of risk

(1) In a prosecution of a person for an offence against section 250 for a contravention of section 218 or 228, the recall order or prohibited product order is sufficient evidence—

(a) of the existence of any risk described in the order; and

(b) that the risk creates or increases a significant risk to personal health or public health.

(2) In a prosecution of a person for an offence against section 262 or 263, the premises restriction order or directions order is sufficient evidence—

(a) of the existence of any risk described in the order; and

(b) that the risk directly or indirectly exposes any individual to a risk of death, serious injury, or serious illness.

(3) In a prosecution of a person for an offence against section 264, the product moratorium order is sufficient evidence—

(a) of the existence of any risk described in the order; and

(b) that the risk does either or both of the following:

(i) creates or increases a significant risk to personal health or public health:

(ii) directly or indirectly exposes any individual to a risk of death, serious injury, or serious illness.

(4) However, subsection (1), (2), or (3) does not apply if there is evidence to the contrary.

325 Evidence of being oversupplied person

(1) In a prosecution of a person for an offence against section 265 for a contravention of section 231(1), the medicine access limitation order is sufficient evidence that the person who is the subject of the order is an oversupplied person.

(2) However, subsection (1) does not apply if there is evidence to the contrary.

Presumptions

326 Presumptions arising from labels

(1) If a package is labelled with a description of its contents, in proceedings under this Act, the package's contents are presumed to conform with that description.

(2) If a package is labelled in a way that identifies a person as having carried out a supply chain activity with the package or its contents, in proceedings under this Act, the person is presumed to have carried out that activity.

(3) However, subsection (1) or (2) does not apply if there is evidence to the contrary.

327 Presumptions about samples

(1) This section applies in relation to a sample taken from an identified quantity of a therapeutic product if the sample—

(a) is taken by a recognised tester at a recognised testing entity (as defined in section 358); and

(b) is taken and dealt with in accordance with a sampling protocol approved by the person designated under that section as being in charge of the entity's testing.

(2) In proceedings under this Act, the sample is presumed to be representative of the specified quantity of the product from which it was taken unless the contrary is proved.

328 Evidence of testing

(1) In civil penalty proceedings, a certificate of testing issued by a recognised tester (as defined in section 358) is sufficient evidence of the matters set out in it unless there is evidence to the contrary.

(2) However, the certificate is admissible in evidence only if—

(a) the Regulator—

(i) serves a copy of the certificate on the defendant at least 10 working days before the hearing at which the certificate is to be given in evidence; and

(ii) at the same time, notifies the defendant that the Regulator does not propose to call the recognised tester as a witness; and

(b) the defendant does not notify the Regulator at least 5 working days before the hearing that the defendant requires the Regulator to call the recognised tester as a witness.

(3) A certificate is not admissible in evidence if the court, on its own motion, directs that the result of the testing must be disregarded unless the result is proved by the oral evidence of the recognised tester.

Guidance note

A certificate or notice for the purpose of this section must be served or given in accordance with the applicable court rules.

Subpart 12—Miscellaneous matters

Injunctions

329 Court may grant injunction

(1) A court may, on application by the Regulator, grant an injunction restraining a person (**person A**) from engaging in conduct of a specified kind that would contravene a provision of this Act.

(2) The court may grant the injunction if satisfied on reasonable grounds that person A—

(a) has engaged in conduct of that kind; or

(b) is likely to engage in conduct of that kind if an injunction is not granted.

(3) The court may grant an interim injunction against person A if it thinks it is desirable to do so.

(4) The court may grant an injunction whether or not person A,—

(a) in the case of subsection (2)(a) or (3), intends to engage again in, or to continue to engage in, conduct of that kind; or

(b) in the case of subsection (2)(b) or (3), has previously engaged in conduct of that kind.

(5) The court may grant an injunction whether or not there is an imminent danger of substantial damage to any other person if person A engages in conduct of that kind.

(6) The court must not make the grant of the injunction conditional on the Regulator giving an undertaking as to damages.

(7) In deciding whether to grant the injunction, the court must not take into account the fact that the Regulator is not required to give an undertaking as to damages.

Other orders available to court

330 When court may make other orders

(1) This section applies if a court—

(a) is sentencing a defendant for an offence against a provision of this Act; or

(b) is making a civil penalty order against a person under section 274; or

(c) is making an order against a defendant under section 21(9) of the Summary Proceedings Act 1957 in relation to an infringement offence.

(2) The court may make an order against the person under 1 or more of sections 331 to 335 if the court thinks it is appropriate to do so.

(3) The order may be made instead of, or in addition to, any other penalty that may be imposed on the person.

(4) Before making an order, the court must give the Regulator and defendant an opportunity to make submissions to the court on the matter.

331 Court may amend, suspend, or cancel 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 proceedings are brought in reliance on section 313.

(2) The court may, by order,—

(a) amend the licence or permit if satisfied that the amendment is one that the Regulator could make under section 171; or

(b) cancel or suspend the licence or permit if satisfied that any of the grounds to suspend or cancel it listed in section 172 or 173 exist.

332 Court may amend or cancel market authorisation

(1) This section applies if the defendant—

(a) is the sponsor of a therapeutic product; or

(b) is a senior manager of a sponsor of a therapeutic product against whom proceedings are brought in reliance on section 313.

(2) The court may, by order,—

(a) amend the product's market authorisation if satisfied that the amendment is one that the Regulator could make under section 138; or

(b) cancel the product's market authorisation if satisfied that any of the grounds to cancel it listed in section 139 exist.

333 Court may order person to pay costs of mitigating risk or dealing with product

(1) This section applies if—

(a) the conduct constituting the contravention that is the subject of the proceedings directly or indirectly creates or increases a significant risk to personal health or public health or might reasonably be expected to do so; and

(b) the Regulator has incurred, or reasonably expects to occur, costs to mitigate that risk.

(2) This section also applies if the Regulator has incurred—

(a) costs in dealing with any therapeutic product or other things for the purposes of the proceedings (such as storage or testing costs); or

(b) seizure-related costs (as defined in section 249) in relation to therapeutic products or other things that were the subject of the offence.

(3) The court may order the defendant to pay to the Regulator an amount not exceeding those costs.

334 Court may make orders about advertising, packages, labelling, and identification

(1) This section applies if the conduct constituting the contravention that is the subject of the proceedings involves the use of identification, labelling, packages, or advertisements for a therapeutic product.

(2) The court may make any orders it thinks are appropriate in relation to the defendant's future use of identification, labelling, packages, or advertisements for therapeutic products.

Examples

Example 1

If the defendant is the sponsor of a therapeutic product, the court might order them—

- not to advertise the product in future unless the Regulator has approved the advertisement; or
- to include particular information in its labelling.

Example 2

If the defendant is an advertiser (but not the product's sponsor), the court might order them—

- not to advertise a certain kind of therapeutic product; or

- not to advertise therapeutic products in a particular way.

335 Court may make orders about forfeiture and seizure

(1) This section applies if the contravention that is the subject of the proceedings involved a specific therapeutic product.

(2) The court may order that the product or anything related to it (such as ingredients or packaging), or both,—

(a) be forfeited to the Crown; or

(b) be disposed of by the defendant (at the defendant's cost) in the way directed by the court or the Regulator.

Notification

336 Notice of court orders

(1) If a court makes an order under any of sections 331 to 335, 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—

(a) convicts a health practitioner or veterinarian of an offence against a provision of this Act; or

(b) makes a civil penalty order against a health practitioner or veterinarian,—

the court registrar must notify the relevant practitioner regulatory body of the conviction or order.

(3) If a court convicts a Crown organisation of an offence against a provision of this Act, the court registrar must notify—

(a) the appropriate Minister (as defined in section 5 of the Public Service Act 2020) or responsible Minister (as defined in section 10 of the Crown Entities Act 2004) as the case requires; and

(b) the chief executive of the Crown organisation (if they are not a party to the proceedings).

Part 9
Regulator

Subpart 1—Therapeutic Products Regulator

337 Therapeutic Products Regulator

(1) There is a Therapeutic Products Regulator.

(2) The chief executive of the Ministry must appoint a person to be the Regulator.

(3) The chief executive must be satisfied on reasonable grounds that the person has the knowledge, skills, and experience to perform the functions and exercise the powers of the Regulator.

(4) The person appointed must be a public service employee (as defined in section 5 of the Public Service Act 2020) of the Ministry (or become employed as such for the purpose of taking up the appointment).

338 Objective of Regulator

The objective of the Regulator is to foster and maintain an independent and effective system to regulate therapeutic products to achieve the purposes of this Act.

339 Functions of Regulator

The Regulator has the following functions:

Regulating therapeutic products

(a) to regulate the availability and use of therapeutic products in accordance with this Act, including by—

(i) issuing market authorisations; and

(ii) granting licences and permits; and

(iii) regulating the carrying on of controlled activities and other supply chain activities:

(b) to carry out post-market surveillance:

(c) to take action to address issues relating to—

(i) the safety, quality, and efficacy of medicines and APIs:

(ii) the safety, quality, and performance of medical devices:

(iii) the safety and quality of NHPs:

(d) to monitor and enforce compliance with this Act:

Engagement with other entities

(e) to foster co-operative and consultative relationships with—

(i) health entities under the Pae Ora (Healthy Futures) Act 2022; and

(ii) regulators or administering agencies for relevant laws (as defined in section 61):

(f) to engage and co-operate with relevant government, local government, and non-government entities, including by sharing information under section 350:

(g) to engage and co-operate with overseas regulators and overseas organisations, including—

(i) by sharing information under section 350; and

(ii) by providing assistance to, and seeking assistance from, those organisations; and

(iii) to facilitate the Regulator being able to rely on their reports, assessments, or decisions, or information received from them (*see* section 354):

(h) to ensure that New Zealand participates in overseas organisations and forums relating to the regulation of therapeutic products:

Information

(i) to collect, analyse, and make available (including to the public) information relating to—

(i) the safety, quality, and efficacy or performance of therapeutic products:

(ii) health benefit claims or other claims made about therapeutic products:

(iii) any other matters relating to therapeutic products:

(j) to provide guidance, advice, and information about therapeutic products to—

(i) persons to whom this Act applies (including sponsors, licensees, permit holders, and persons in the supply chain):

(ii) other persons and entities who are concerned with therapeutic products:

(iii) the public:

(k) to issue official statements under section 240:

Engagement with Māori and other groups

(l) to engage with Māori and other population groups in a manner that reflects their needs and aspirations in relation to therapeutic products:

Advice to chief executive and Minister

(m) to monitor the adequacy and performance of, and funding for, the regulatory system for therapeutic products and to provide advice about those matters to the chief executive of the Ministry and the Minister:

(n) to provide any other relevant information and advice about therapeutic products to the chief executive of the Ministry and the Minister:

Other functions

(o) to perform any other functions conferred on the Regulator under this or any other Act.

Guidance note

The disclosure of personal information is subject to the Privacy Act 2020 and section 353.

The disclosure of protected active ingredient information is prohibited by subpart 3 of Part 4.

340 Performance of functions and exercise of powers

(1) In performing their functions and exercising their powers, the Regulator—

(a) must act independently of the chief executive of the Ministry and the Minister; but

(b) is subject to any general policy directions given by the Minister that affect therapeutic products and are consistent with the purpose of this Act and the principles set out in section 4.

(2) The Regulator is accountable to the chief executive of the Ministry for the Regulator's performance of their functions and exercise of their powers.

(3) The Regulator must have arrangements in place to avoid or manage conflicts of interest relating to the performance of their functions and exercise of their powers.

(4) The Regulator must ensure they have the capacity and capability—

(a) to understand and give effect to the principles of te Tiriti o Waitangi/the Treaty of Waitangi; and

(b) to understand and take account of mātauranga Māori and Māori perspectives in relation to therapeutic products.

341 Regulatory strategy for performance of functions and exercise of powers

(1) The Regulator must have a regulatory strategy that sets out how they will perform their functions and exercise their powers.

(2) The strategy must set out the following:

(a) key areas of focus, including the key risks being targeted in those areas:

(b) the regulatory approach the Regulator will take in performing their functions and exercising their powers:

(c) how the Regulator's performance of their functions and exercise of their powers will be assessed:

(d) how the Regulator will give effect to the principles of te Tiriti o Waitangi/the Treaty of Waitangi in performing their functions and exercising their powers:

(e) how the strategy will be reviewed and, if appropriate, updated:

(f) any other information required by the regulations.

(3) The Regulator must review and, if appropriate, update the strategy at least once every 3 years.

(4) The Regulator must make the strategy publicly available.

Guidance note

Public availability requirements are set out in section 388.

Subpart 2—Cost recovery

342 Recovery of costs

(1) The Regulator, the chief executive of the Ministry, and the Minister must take all reasonable steps to ensure that the costs of administering this Act that are not provided for by money appropriated by Parliament for that purpose are recovered in accordance with this subpart by way of fees, levies, or otherwise.

(2) The **costs of administering this Act** means the direct and indirect costs incurred or reasonably expected to be incurred by the Regulator in performing their functions and exercising their powers under this Act.

343 Principles for cost recovery

Recovery of the costs of administering this Act must be done in a way that is, generally and to the extent practicable,—

(a) equitable, in that the costs of performing a function or exercising a power should be recovered from the users or beneficiaries of the function or power at a level commensurate with their use or benefit (although strict apportionment of the costs based on usage is not required); and

(b) efficient, in that the costs of administering the Act should be allocated and recovered in a way that ensures that maximum benefits are delivered at minimum cost; and

(c) justifiable, in that costs should be recovered only if they are actually and reasonably incurred by the Regulator in performing a function or exercising a power; and

(d) transparent, in that costs should be identified and allocated to a particular identifiable performance of a function or exercise of a power when it is performed or exercised.

344 Regulations about fees and levies

(1) The regulations may set fees and levies for the purposes of this Act.

(2) The regulations may set out any of the following:

(a) the matters in respect of which fees or levies are payable:

(b) the amount of a fee or levy or the method by which it is to be calculated (*see* section 345):

(c) who is liable to pay a fee or levy:

(d) when a fee or levy must be paid:

(e) how a fee or levy may be recovered (but without limiting section 348):

(f) the consequences of failing to pay a fee or levy (including, for example, a monetary penalty, a liability to pay interest, or the right of the Regulator to refrain from performing a function or exercising a power) (*see also* section 391).

(3) The regulations may authorise the Regulator to waive or refund a fee or levy in a particular case, and may set out the circumstances in which they may do so.

(4) If the regulations provide for a fee or levy to be calculated using a formula, they may provide for the value of a variable in the formula to be set by the rules.

345 Methods of setting fees and levies

(1) A fee or levy may be set using any of the following methods:

(a) a fixed amount, or a method of calculating or ascertaining a fixed amount:

(b) an amount based on a scale or formula or at a rate determined on a unit basis:

(c) recovery of amounts actually expended in performing a function or exercising a power:

(d) a deposit (which may be refundable) to be paid before a function is performed or a power is exercised:

(e) payment in advance of the estimated actual and reasonable costs to be incurred in the performance of a function or exercise of a power (with a reconciliation against actual costs afterwards).

(2) A fee or levy may be set at a level or in a way that—

(a) is determined by calculations that involve an averaging of costs:

(b) takes into account costs relating to the performance of a function or exercise of a power in relation to a class of persons of which the person liable to pay the fee or levy is a member (even if the cost does not relate directly to that person).

(3) A fee or levy in respect of a financial year may be set to make up any shortfall in cost recovery during the preceding 4 financial years or to allow for any over-recovery during that period (including any estimated shortfall or over-recovery for the immediately preceding year).

346 Annual fees and levies

(1) Regulations that set an annual fee or levy in respect of a financial year—

(a) must be made before the start of the financial year; and

(b) apply in that year and all subsequent years until revoked or replaced, unless the regulations say otherwise.

(2) However, the regulations may be made or amended during the financial year if—

(a) the fee or levy is reduced, removed, or restated without substantive alteration; or

(b) in the case of an amendment, it is to correct an error; or

(c) in the case of an increase or the imposition of a new fee or levy, the persons required to be consulted under section 395(3)(a) substantially agree with the increase or imposition.

347 Preconditions for making regulations imposing fees or levies

(1) The Minister must not recommend that regulations be made imposing a fee or levy unless satisfied on reasonable grounds that—

(a) the principles set out in section 343 have been taken into account in determining how costs are to be recovered and the amount or method of calculating the fee or levy; and

(b) the fee or levy is set in accordance with section 345; and

(c) if applicable, the regulations comply with section 346; and

(d) the fee or levy is otherwise appropriate and proportionate.

(2) For the purposes of section 395, in relation to regulations imposing fees or levies, the Regulator must consult on the proposed methods and levels of cost recovery, but need not consult on each specific fee or levy (so long as they are reasonably within the scope of any general consultation).

348 Fees and levies payable to Regulator

(1) A fee or levy is payable to the Regulator.

(2) An unpaid fee or levy may be recovered by the Regulator in a court of competent jurisdiction as a debt due to the Regulator.

(3) A dispute between a person and the Regulator about the person's liability to pay a fee or levy does not affect—

(a) the person's obligation to pay the fee or levy; or

(b) any other consequences that might result from the non-payment.

Example

An example of a consequence that might result from non-payment is the Regulator cancelling a market authorisation under which a person is the sponsor for non-payment of a levy that is payable by sponsors.

349 Three-yearly review of cost recovery

(1) The Regulator must review the levels and methods of cost recovery at least once every 3 years.

(2) In carrying out the review, the Regulator must—

(a) consult the persons (or representatives of the persons) they think are likely to be substantially affected by the levels and methods of cost recovery; and

(b) give those persons an opportunity to comment on the matters under review.

(3) The Regulator must make the results of the review publicly available.

Guidance note

Public availability requirements are set out in section 388.

Subpart 3—Information

350 Sharing of information with regulatory entities, 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 of the Regulator's functions or exercise of their powers under this Act; and

(b) thinks may assist the recipient in performing their functions or exercising their powers.

(2) A regulatory entity may give to the Regulator any information that the entity—

(a) holds in relation to the performance of the entity's functions or exercise of their powers; and

(b) thinks may assist the Regulator in performing the Regulator's functions or exercising their powers under this Act.

(3) The Regulator or regulatory entity may give the information subject to any conditions they think are appropriate.

(4) The Regulator must not give information to an overseas regulator or overseas organisation unless satisfied on reasonable grounds 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, the privacy of the person to whom it relates.

(5) This section applies despite anything to the contrary in any contract, deed, or document.

(6) In this section, **regulatory entity** means any of the following entities:

(a) the Ministry:

(b) the Accident Compensation Corporation:

(c) the Commerce Commission:

(d) Customs:

(e) the Environmental Protection Authority:

(f) the Health and Disability Commissioner:

(g) a health entity under the Pae Ora (Healthy Futures) Act 2022:

(h) the Inland Revenue Department:

(i) the New Zealand Police:

(j) a practitioner regulatory body:

(k) the Serious Fraud Office:

(l) WorkSafe New Zealand:

(m) the department responsible for the administration of a relevant law (as defined in section 61):

(n) an entity with regulatory functions under an Act that the regulations say is a regulatory entity.

Guidance note

The disclosure of personal information is subject to the Privacy Act 2020 and section 353.

The disclosure of protected active ingredient information is prohibited by subpart 3 of Part 4.

351 Customs information to be given on request

(1) The Regulator may request the chief executive of Customs to give the Regulator any information of a kind referred to in section 316(2)(a) or (b)(i) or (vii) of the Customs and Excise Act 2018 that might assist the Regulator to perform their functions or exercise their powers under this Act.

(2) The chief executive of Customs must comply with the request.

352 Information not to be disclosed

(1) An information holder must not disclose relevant information (or direct anyone else to do so) unless one of the following applies:

(a) the information is publicly available from another source:

(b) the information is in a statistical or summary form:

(c) the information is disclosed—

(i) by the Regulator or an inspector in the course of performing their functions or exercising their powers under this Act; or

(ii) by a recognised testing entity for the purposes of this Act; or

(iii) by a worker in the course of doing their work for the Regulator or recognised testing entity:

(d) the information is disclosed by the Regulator in accordance with section 350 (sharing of information with regulatory entities, etc):

(e) the information is disclosed—

(i) to a person who the Regulator is satisfied on reasonable grounds has a proper interest in receiving it; and

(ii) if it is confidential or personal information, after the Regulator is satisfied on reasonable grounds that appropriate protections will be in place to maintain its confidentiality or the privacy of the person to whom it relates:

(f) if it is confidential or personal information, it is disclosed with the consent of the person to whom it relates or is confidential:

(g) the disclosure of the information is required or authorised by law.

(2) In this section,—

information holder means the Regulator, an inspector, a recognised testing entity, or a person who works for the Regulator or a recognised testing entity

relevant information means information that an information holder obtains, or obtains access to, in the course of (as the case requires)—

(a) performing their functions or exercising their powers under this Act; or

(b) carrying out a test for the purposes of this Act; or

(c) doing their work for the Regulator or a recognised testing entity.

Guidance note

The disclosure of personal information is subject to the Privacy Act 2020 and section 353.

The disclosure of protected active ingredient information is prohibited by subpart 3 of Part 4.

Not complying with this section may be an offence (*see* section 267).

353 Personal information protected by Privacy Act 2020

(1) This section applies if—

(a) a provision of this Act requires or permits the Regulator to disclose personal information; and

(b) in the absence of that provision, the Privacy Act 2020 would prohibit that disclosure.

(2) The Regulator must not disclose the information unless satisfied on reasonable grounds that the disclosure is reasonably necessary for the purposes of this Act.

(3) A person whose personal information is disclosed may make a complaint about the disclosure under Part 5 of the Privacy Act 2020 as if the definition of an interference with the privacy of an individual in section 69 of that Act included a breach of subsection (2).

(4) However, a disclosure that is permitted by subsection (2) is not an interference with the person's privacy.

Subpart 4—Decision making and exercise of powers

354 Regulator may rely on decisions, etc, of designated entities

(1) In evaluating a therapeutic product or making a decision under this Act, the Regulator may rely on reports, assessments, or decisions made by, or information received from, an entity designated under subsection (2).

(2) The Regulator may, by Regulator's notice, designate any of the following for the purposes of subsection (1):

(a) an overseas regulator:

(b) an overseas organisation:

(c) any other person or body that the Regulator is satisfied on reasonable grounds has knowledge of, and expertise in, a relevant subject matter.

355 Decisions relating to rongoā

(1) This section applies if—

(a) the Regulator proposes to perform a function or exercise a power under Part 7 or 8; and

(b) any of the following are relevant to the performance of the function or exercise of the power:

(i) whether an NHP is a rongoā product:

(ii) whether a person is a rongoā practitioner:

(iii) whether a service or an activity is a rongoā service or activity:

(iv) whether there is the evidence referred to in section 62(3)(b) of the use of a rongoā product for a particular purpose.

(2) Before performing the function or exercising the power, the Regulator must—

(a) notify the rongoā advisory committee of the Regulator's intention to do so; and

(b) allow the committee a reasonable time (specified in the notice) to give its advice to the Regulator; and

(c) take into account any advice given by the committee in that time.

(3) However, the Regulator need not comply with subsection (2) if satisfied on reasonable grounds that not doing so is necessary—

(a) because of a significant risk to any individual of death, serious injury, or serious illness; or

(b) in the case of a decision relating to the exercise of a power under Part 8, because of a significant risk that complying with subsection (2) could defeat the purpose for which the power is to be exercised.

356 Inspectors

(1) The Regulator may, by written notice, appoint an individual, or all individuals in a class of individuals, as inspectors if satisfied that the individual, or all individuals in that class, are suitably qualified and trained to be inspectors.

(2) An inspector's powers are subject to any conditions or limitations specified in their appointment notice.

(3) An inspector must also comply with any directions given to them by the Regulator.

(4) However, anything done by an inspector is not invalid merely because those conditions, limitations, or directions were not complied with.

(5) The Regulator may suspend or revoke an inspector's appointment at any time.

357 Identification cards

(1) The Regulator must give each inspector an identity card that—

(a) identifies them as an inspector; and

(b) sets out the following:

(i) their name:

(ii) the powers they are authorised to exercise:

(iii) the duration of their appointment (which may be until it is revoked):

(iv) any other information required by the regulations.

(2) When performing a function or exercising a power under this Act, an inspector must produce their identity card for inspection when reasonably requested to do so.

(3) A person must return their identity card when they cease to be an inspector.

Guidance note

Section 214 of this Act and section 131 of the Search and Surveillance Act 2012 impose identification and notice requirements on an inspector entering and searching a place.

358 Recognised testing entity and recognised tester

(1) The Regulator may, by Regulator's notice, designate—

(a) an entity as one that may carry out tests on therapeutic products for the purposes of this Act (a **recognised testing entity**):

(b) a person who works for the entity as the person in charge of the entity's testing of those products.

(2) The person in charge may, by written notice, designate any other worker of the entity as a person who may carry out those tests.

(3) A **recognised tester** means a person designated under subsection (1)(b) or (2).

(4) The Regulator must not designate an entity as a recognised testing entity unless satisfied on reasonable grounds that—

(a) the entity is independent of the Regulator and the sponsors of the products of the kind they are designated to test; and

(b) the entity has adequate and suitable premises, equipment, processes, and procedures, and suitably qualified workers, to enable it to carry out the tests it is designated to carry out; and

(c) the entity has appropriate protections in place to maintain the confidentiality of information relating to products they test.

359 Delegation

(1) The Regulator may delegate any of their functions and powers (other than this power of delegation) to any person.

(2) A delegation must be made in writing and may be subject to any conditions the Regulator thinks are appropriate.

(3) The delegate may perform or exercise a delegated function or power in the same way, subject to the same restrictions, and with the same effect as if the delegate were the Regulator, unless the delegation provides otherwise.

(4) The delegation does not affect the Regulator's—

(a) ability to perform the function or exercise the power; or

(b) responsibility for anything done in the performance of the function or exercise of the power.

(5) A person purporting to act as a delegate—

(a) is presumed to be a delegate acting within the scope of their delegation in the absence of evidence to the contrary; and

(b) must produce evidence of their delegation if reasonably requested.

(6) A delegation made by a person who ceases to hold office as the Regulator continues to have effect as if it were made by the person who is the Regulator from time to time.

360 Use of automated systems

(1) The Regulator may arrange for the use of an automated electronic system to carry out actions (including evaluating applications and making decisions) that are part of performing their functions or exercising their powers under this Act.

(2) The Regulator may do so only if satisfied on reasonable grounds that—

(a) the system has the capacity to do the action with reasonable reliability; and

(b) a process is in place under which a person affected by the action can have the action reviewed by the Regulator without undue delay.

(3) Before making an arrangement about a system that will involve collecting or using personal information, the Regulator must consult the Privacy Commissioner.

Example

The Regulator may establish an online system to enable applications for market authorisations for NHPs to be assessed and those market authorisations to be issued.

361 Effect of use of automated system

(1) An action carried out by an automated electronic system—

(a) is taken to have been carried out by the Regulator; and

(b) is not invalid by reason only of having been carried out by the system.

(2) If the system carries out the action in a way that is clearly incomplete or wrong, the Regulator may complete or redo the action.

362 Opportunity to comment

(1) If this Act requires the Regulator 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 their 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; and

(c) take into account any submissions made in that time.

(2) However, the Regulator need not comply with subsection (1) if—

(a) all of the persons who they 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 on reasonable grounds that exercising the power without complying with subsection (1) is necessary because of a significant risk to personal health or public health.

363 Notice and reasons for decision by Regulator

(1) Subsections (2) and (3) apply if a provision of this Act requires the Regulator to notify (whether by serving a notice or otherwise) a person of a decision made by the Regulator.

(2) The notification must set out—

(a) the Regulator's decision; and

(b) the reasons for the decision or a statement that the person is entitled to ask for a statement of reasons; and

(c) the person's right to have the decision reviewed under subpart 6 (if applicable).

(3) The Regulator must serve or give (as applicable) 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 their reasons for the decision (whether or not the person has been given notice of the decision).

(5) If asked, the Regulator must give the person a statement of their reasons for the decision—

(a) within the time set out in the regulations; or

(b) if no time is specified, within a reasonable time of being asked.

364 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 their powers under subpart 2 of Part 7 to obtain information or things to assist the requesting body to perform the body's functions or exercise its powers.

(2) The Regulator may comply with a request only if satisfied on reasonable grounds that—

(a) compliance will not substantially affect the Regulator's performance of the Regulator's functions or exercise of their powers; 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 on reasonable grounds 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, the privacy of the person to whom it relates.

Guidance note

The disclosure of personal information is subject to the Privacy Act 2020 and section 353.

The disclosure of protected active ingredient information is prohibited by subpart 3 of Part 4.

Subpart 5—Advisory committees

Rongoā advisory committee

365 Rongoā advisory committee

(1) There is a rongoā advisory committee.

(2) The committee consists of the members appointed under section 367.

(3) The Ministry must provide administrative support for the committee.

366 Functions of rongoā advisory committee

(1) The rongoā advisory committee has the following functions:

(a) to advise the Regulator on matters relating to the Regulator's performance of their functions and exercise of their powers in relation to rongoā (including the matters referred to in section 355(1)):

(b) to advise the Minister and Regulator on other matters relating to this Act in relation to rongoā:

(c) to give any other advice requested by the Minister or Regulator:

(d) any other advisory functions conferred on the committee by the Minister by written notice.

(2) The committee may publish guidelines for rongoā practitioners, and other information about rongoā, on matters connected with this Act.

(3) The Minister must give a copy of any notice given under subsection (1)(d) to the Regulator.

367 Appointment of members of rongoā advisory committee

(1) The joint Ministers must appoint the number of persons they think appropriate to be members of the rongoā advisory committee.

(2) The joint Ministers must be satisfied on reasonable grounds that the persons appointed have, collectively, the knowledge, skills, and experience in the following matters to enable the committee to perform its functions:

(a) rongoā and mātauranga Māori; and

(b) this Act; and

(c) the machinery of government; and

(d) any other matters that the joint Ministers think are appropriate.

(3) Before appointing a person, the joint Ministers must consult—

(a) any persons that an Order in Council requires them to consult; and

(b) the Regulator; and

(c) any other persons with knowledge, skills, and experience in matters relevant to the appointment as the joint Ministers think appropriate.

(4) Committee members are appointed on the terms and conditions determined by the joint Ministers.

(5) An Order in Council made under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

(6) In this section, **joint Ministers** means the following Ministers acting jointly:

(a) the Minister as defined in section 14; and

(b) the Minister of the Crown who, under the authority of a warrant or with the authority of the Prime Minister, is responsible for the administration of the Ministry of Maori Development Act 1991.

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

This note is not part of the Act.

368 Procedure of rongoā advisory committee

(1) The rongoā advisory committee must act in accordance with—

(a) the principles of natural justice; and

(b) if giving advice about a particular person or particular product, section 369.

(2) The committee must have arrangements in place to avoid or manage conflicts of interest relating to the performance of its functions.

(3) The committee may—

(a) consult any person who the committee thinks can give it relevant information; and

(b) otherwise obtain any information it thinks is relevant from any source.

(4) The committee may otherwise determine its own procedure.

369 Advice about particular person or product

(1) This section applies to advice about a particular person or a particular product (such as advice on the matters referred to in section 355(1)).

(2) Before giving the advice, the rongoā advisory committee must—

(a) notify the person or manufacturer of the product of its intention to give the advice; and

(b) allow them a reasonable time (specified in the notice) to make submissions to the committee on the matter; and

(c) take into account any submissions made in that time.

(3) However, the committee need not comply with subsection (2) if satisfied on reasonable grounds that not doing so is necessary—

(a) because of a significant risk to any individual of death, serious injury, or serious illness; or

(b) in the case of advice relating to the exercise of a power under Part 8, because of a significant risk that complying with subsection (2) could defeat the purpose for which the power is to be exercised.

(4) The committee must give the person or manufacturer a copy of the advice given to the Regulator or Minister.

Other advisory committees

370 Other advisory committees

(1) The Regulator may establish 1 or more advisory committees (in addition to the rongoā advisory committee) to advise the Regulator on matters relating to the Regulator's performance of their functions and exercise of their powers.

(2) The Regulator must—

(a) determine the functions of each advisory committee; and

(b) appoint such number of persons as committee members as the Regulator considers appropriate.

(3) The Regulator must be satisfied on reasonable grounds that the persons appointed have the knowledge, skills, and experience to enable the committee to perform its functions (including knowledge of mātauranga Māori when it is relevant).

(4) Committee members are appointed on the terms and conditions determined by the Regulator.

All advisory committees

371 Advisory committee details to be made publicly available

(1) The Regulator must make the following information about the rongoā advisory committee and each other advisory committee publicly available:

(a) its name:

(b) its functions:

(c) the names of its members.

(2) However, the Regulator is not required to make a committee member's name publicly available if satisfied on reasonable grounds that doing so would be likely to—

(a) endanger the safety of any person; or

(b) adversely affect the operation of the committee.

(3) If the Regulator does not make a name publicly available, they must make their reasons for deciding not to do so publicly available.

Subpart 6—Review of Regulator's decisions

372 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 made under a provision listed in Schedule 3; and

(b) the person is identified in Schedule 3 as a person who may apply for a review of that decision.

(2) An applicant must—

(a) apply to the Regulator—

(i) within 30 working days after notice of the decision is served on or given to (as applicable) the applicant; and

(ii) in the way set out in the regulations; and

(b) comply with any procedural requirements in the regulations; and

(c) pay the fee (if any) for making the application set by regulations made for section 344.

Guidance note

Sections 363 and 389 set out requirements for giving notice of decisions and service of documents.

373 Regulator to convene review panel

(1) On receiving an application to have a decision (the **original decision**) reviewed, the Regulator must convene a review panel in accordance with any requirements in the regulations.

(2) The review panel must consist of at least 3 persons who—

(a) the Regulator is satisfied have the knowledge, skills, and experience to enable the panel to perform its functions (including knowledge of mātauranga Māori when that is relevant); and

(b) were not involved in making the original decision; and

(c) do not have any conflict of interest in relation to the original decision.

(3) The review panel must include at least 1 lawyer (as defined in section 6 of the Lawyers and Conveyancers Act 2006) with at least 7 years' legal experience.

374 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 procedural requirements in the regulations.

(3) The review panel may otherwise determine its own procedure.

375 Decision on review

(1) After reviewing the original decision, the review panel must either—

(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.

376 Appeal to District Court

(1) If the review panel confirms the original decision, 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; and

(b) the Regulator makes 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 rules made under section 228 of the District Court Act 2016.

377 Other proceedings

(1) Applying for a review of a decision under this subpart does not affect any other right any person may have to commence proceedings in any court or tribunal.

(2) However, if such proceedings are commenced in relation to the matters that are the subject of the review, the review proceedings are stayed until the other proceedings are determined and all appeal rights exhausted (unless the court or tribunal orders otherwise).

Part 10
Administrative matters

Subpart 1—Therapeutic products register

378 Therapeutic products register

(1) The Regulator must maintain a therapeutic products register.

(2) The register must include—

(a) all therapeutic products—

(i) that have a market authorisation; or

(ii) for which an application for a market authorisation has been made but not yet determined, but only if the product is being supplied in New Zealand by the applicant before the application is made; or

(iii) for which a market authorisation has been refused; or

(iv) for which a market authorisation has ceased; and

(b) all licences and permits; and

(c) any other information required by the regulations.

(3) For each product, licence, permit, or thing, the register must include the information required by the regulations.

(4) The register may include any other information that the Regulator thinks is appropriate (including information about a product or thing that is not required to be included in the register).

(5) The Regulator must make the register publicly available.

Guidance note

Public availability requirements are set out in section 388.

Subpart 2—Applications, notices, etc

Applications

379 Applications to Regulator

(1) This section and sections 380 to 386 apply to an application to the Regulator for the purposes of this Act, other than an application for review under section 372.

(2) The applicant must—

(a) make the application in the way set out in the rules; and

(b) comply with any procedural requirements in the rules; and

(c) pay the fee (if any) for making the application set by regulations made for the purposes of section 344.

(3) The application must include the information required by the rules.

380 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 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—

(a) be made in writing; and

(b) set out the date by which it must be complied with (which must allow the applicant a reasonable time to comply).

(3) After making a request, the Regulator may defer consideration of the application until the request is complied with.

381 Regulator may obtain information

(1) In assessing an application, the Regulator may obtain any other information they think is appropriate from any source.

(2) This section is subject to subpart 3 of Part 4.

382 Information is part of application

Any information that the applicant gives to the Regulator in relation to the application (whether given in or with the application, in response to a request under section 380, or otherwise) is taken to be part of the application.

Guidance note

One of the grounds for cancelling a market authorisation, licence, or permit is that the application for it included misleading information. Because of this section, that extends to all information that the applicant gives to the Regulator in relation to the application.

383 Regulator may split application for licence or permit

(1) This section applies if—

(a) a person applies for a licence or permit; and

(b) the Regulator thinks that the controlled activities or other things to which the application relates would be more appropriately regulated using—

(i) 2 or more licences or permits; or

(ii) a licence and a permit; or

(iii) a permit rather than a licence or a licence rather than a permit; or

(iv) 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 they think is appropriate, and may grant (or refuse to grant) 1 or more licences or permits accordingly.

384 Regulator may reject non-complying application

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

(a) section 379 is not complied with; or

(b) a request made under section 380 is not complied with in the specified time; or

(c) the Regulator is satisfied on reasonable grounds that any information in the application is misleading information.

385 Opportunity to comment before adverse decision

(1) The Regulator must not make an adverse decision on an application unless they have given the applicant an opportunity to comment.

(2) An **adverse decision**, in relation to an application, means a decision—

(a) to reject or refuse the application; or

(b) to grant the application on terms or conditions that are materially more restrictive than those sought by the applicant; or

(c) if the application is for a standard authorisation for a medicine or medical device, to issue a provisional authorisation for the medicine or device.

386 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

387 Notifying the 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 set out in the rules; and

(b) comply with any procedural requirements in the rules; and

(c) pay the fee (if any) set by regulations made for the purposes of section 344.

(2) The Regulator may refuse to accept the notification if subsection (1) is not complied with.

(3) This section does not apply to any notice required to be given to the Regulator in connection with proceedings in a court or tribunal (*see instead* the applicable court or tribunal rules).

388 Making document or information publicly available

(1) If the Regulator is required under this Act to make a document or other information **publicly available**, they must publish it—

(a) on the Regulator's website; and

(b) in a way that makes its content—

(i) fully searchable; and

(ii) accessible to members of the public at all reasonable times free of charge.

(2) The Regulator must publish the document or other information as soon as practicable after being required to make it available.

(3) However, the Regulator is not required to make it publicly available if it could properly be withheld under the Official Information Act 1982 if a request for it were made under that Act.

Guidance note

The disclosure of personal information is subject to the Privacy Act 2020 and section 353.

The disclosure of protected active ingredient information is prohibited by subpart 3 of Part 4.

389 Service of documents

(1) A document that is required under this Act to be served on a person (including the Regulator) must be served in a way set out in the regulations.

(2) The document is taken to have been served at the time set out in the regulations.

(3) However, this section does not apply to—

(a) infringement notices and related notices, which must be served in accordance with section 286 of this Act and the Summary Proceedings Act 1957; or

(b) any document that is served on a person in connection with proceedings in a court or tribunal (*see instead* the applicable court or tribunal rules).

Subpart 3—Regulations, rules, Regulator's notices, and exemptions

390 Regulations

(1) The Governor-General may, by Order in Council made on the recommendation of the Minister, make regulations—

(a) providing for anything that this Act says may or must be provided for by regulations; and

(b) providing for anything incidental that is necessary for carrying out, or giving full effect to, this Act.

(2) If a provision of this Act allows the Regulator to make rules or a Regulator's notice, the regulations may set out criteria or requirements relating to the rules or notice for the purposes of section 392(3) or 393(3).

(3) The Minister must not recommend that regulations be made unless satisfied on reasonable grounds that they are appropriate and proportionate, having regard to the likely benefits of, and risks associated with, the therapeutic products in relation to which they apply.

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

(5) Regulations made under this section are secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

Guidance note

Consultation requirements are set out in section 395.

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

This note is not part of the Act.

391 Regulations relating to offences

Offences for contravention of regulations

(1) The regulations may make a contravention of the regulations an offence and set out the penalty for the offence (but for infringement offences, *see* subsection (5)).

(2) The maximum penalty for the offence must not be more than,—

(a) if the offence involves knowledge, recklessness, or any other state of mind, a fine not exceeding,—

(i) if the person who commits the offence is an individual, $30,000; or

(ii) otherwise, $170,000; or

(b) otherwise, a fine not exceeding,—

(i) if the person who commits the offence is an individual, $10,000:

(ii) otherwise, $50,000.

Infringement offences for contravention of provision of Act

(3) For an infringement offence against section 281 for a contravention of a provision listed in that section, the regulations may set out—

(a) an infringement fee of not more than 5% of the strict liability penalty (or, if there is no strict liability offence, $1,000); and

(b) a fine of not more than the strict liability penalty (or, if there is no strict liability offence, $5,000).

(4) In subsection (3), the **strict liability penalty** for an infringement offence for a contravention of a provision is the maximum fine that may be imposed on a person convicted of an offence under subpart 3 of Part 8 for a contravention of the same provision.

Infringement offences for contravention of regulations

(5) The regulations may make a contravention of the regulations an infringement offence and set—

(a) an infringement fee of not more than $1,000; and

(b) a fine of not more than $5,000.

392 Rules

(1) The Regulator may make rules providing for anything that this Act says must or may be provided for by rules.

(2) The Regulator must not make rules unless satisfied on reasonable grounds that they are appropriate and proportionate, having regard to the likely benefits of, and risks associated with, the therapeutic products in relation to which they apply.

(3) The Regulator must not make rules unless the Regulator—

(a) is satisfied on reasonable grounds that any criteria in the regulations are met; and

(b) complies with any other requirements in the regulations about the matter in respect of which the rules are being made.

(4) If a Regulator's notice is inconsistent with the rules, the rules prevail to the extent of the inconsistency.

(5) Rules made under this section are secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

Guidance note

Regulations setting criteria and requirements for the purposes of subsection (3) may be made under section 390(2).

Consultation requirements are set out in section 395.

Legislation Act 2019 requirements for secondary legislation made under this section

Publication	The maker must publish it in accordance with the Legislation (Publication) Regulations 2021	LA19 s 74(1)(aa)
Presentation	The Minister must present it to the House of Representatives	LA19 s 114
Disallowance	It may be disallowed by the House of Representatives	LA19 ss 115, 116

This note is not part of the Act.

393 Regulator's notices

(1) The Regulator may make notices under this section providing for anything that this Act or the regulations say may or must be provided for by Regulator's notice.

(2) The Regulator must not make a Regulator's notice unless satisfied on reasonable grounds that it is appropriate and proportionate, having regard to the likely benefits of, and risks associated with, the therapeutic products in relation to which it applies.

(3) The Regulator must not make a Regulator's notice unless the Regulator—

(a) is satisfied on reasonable grounds that any criteria in the regulations are met; and

(b) complies with any other requirements in the regulations about the matter in respect of which the notice is being made.

(4) 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 the basis on which they are satisfied of the matters in subsection (2)).

(5) A Regulator's notice must set out the date on which it comes into force (which must be after the date on which it is made publicly available under subsection (4)).

(6) A Regulator's notice—

(a) comes into force at the beginning of the date set out 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.

(7) A Regulator's notice may incorporate material by reference in accordance with sections 63 to 66 and Schedule 2 of the Legislation Act 2019 as if the notice were secondary legislation (but *see also* section 396).

Guidance note

Regulations setting criteria and requirements for the purposes of subsection (3) may be made under section 390(2).

Consultation requirements are set out in section 395.

Public availability requirements are set out in section 388.

394 Exemptions

(1) The Regulator may exempt—

(a) a specific therapeutic product or other thing or a class of products or things from the application of any provision of this Act; or

(b) a class of persons from compliance with any provision of this Act.

(2) However, the Regulator must not do so unless satisfied on reasonable grounds that,—

(a) if the exemption relates to a therapeutic product, the exemption is appropriate and proportionate, having regard to the likely benefits of, and risks associated with, the product; and

(b) granting the exemption is a necessary or desirable way to address the matter that gave rise to the exemption; and

(c) the extent of the exemption is not broader than is reasonably necessary to address that matter.

(3) An exemption must set out in it—

(a) the date on which it comes into force (which must be after the date on which it is published under the Legislation Act 2019); and

(b) the date on which it expires (which must not be more than 5 years after it comes into force).

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

(5) A statement of the Regulator's reasons for granting the exemption (including the basis on which they are satisfied of the matters in subsection (2)) must be published with it.

Guidance note

Consultation requirements are set out in section 395.

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

This note is not part of the Act.

395 Consultation

(1) The Regulator must comply with subsections (3) to (6) before—

(a) recommending that the Minister recommend that regulations be made; or

(b) making any other instrument.

(2) The Minister must not recommend that regulations be made unless satisfied on reasonable grounds that the Regulator has complied with subsections (3) to (6).

(3) The Regulator must—

(a) consult the persons (or representatives of the persons) who the Regulator thinks are likely to be substantially affected by the instrument; and

(b) consult the persons (or representatives of the persons) who the Regulator thinks have knowledge, skills, and experience of any mātauranga Māori that is relevant to the instrument; and

(c) give them an opportunity to comment.

(4) If the instrument relates specifically to health practitioners, veterinarians, or persons who work for them, the persons consulted must include the relevant practitioner regulatory body.

(5) If the instrument relates specifically to rongoā, the Regulator must seek the advice of the rongoā advisory committee and take its advice into account.

(6) However, the Regulator need not comply with subsections (3) to (5) if satisfied on reasonable grounds that making the instrument without consultation is necessary because of a risk to any individual of death, serious injury, or serious illness.

(7) A failure to comply with this section does not affect the validity of the instrument.

(8) In this section, **instrument** means regulations, rules, a Regulator's notice, or an exemption under section 394.

396 Incorporation by reference

(1) This section applies to material incorporated by reference—

(a) into the regulations or rules or an exemption in reliance on sections 63 to 66 and Schedule 2 of the Legislation Act 2019; or

(b) into a Regulator's notice in reliance on section 393(7).

(2) The references in Schedule 2 of the Legislation Act 2019 to the administering agency or the chief executive of that agency are taken to refer to the Regulator.

Subpart 4—Review of Act

397 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 and make it publicly available as soon as practicable after it is completed.

Guidance note

Public availability requirements are set out in section 388.

Part 11
Repeal, revocations, and amendments to other enactments

Subpart 1—Repeal and revocations

398 Repeal and revocations

(1) The Sunscreen (Product Safety Standard) Act 2022 (2022 No 4) is repealed.

(2) The following secondary legislation is revoked:

(a) Dietary Supplements Regulations 1985 (SR 1985/208):

(b) Medicines Regulations 1984 (SR 1984/143):

(c) Medicines (Approved Laboratories and Analysts in Charge) Notice 2000 (SR 2000/173):

(d) Medicines (Database of Medical Devices) Regulations 2003 (SR 2003/325):

(e) Medicines (Designated Pharmacist Prescribers) Regulations 2013 (SR 2013/237):

(f) Medicines (Designated Prescriber—Dietitians) Regulations 2015 (LI 2015/149):

(g) Medicines (Designated Prescriber—Registered Nurses) Regulations 2016 (LI 2016/140):

(h) Medicines (Related Products (Exempted Foods)) Regulations 2003 (SR 2003/371):

(i) Medicines (Standing Order) Regulations 2002 (SR 2002/373).

399 Part repealed

This Part is repealed on the day after the date on which section 68 comes into force.

Subpart 2—Amendments to Food Act 2014 if section 398 does not commence on or before 1 March 2026

400 Principal Act

(1) This subpart amends the Food Act 2014.

(2) However, if section 398 of this Act comes into force on or before 1 March 2026, this subpart has no effect and is repealed on that date.

Guidance note

More amendments are made to the Food Act 2014 by section 441 and Schedule 4.

401 Section 413 amended (Overview of transitional provisions)

In section 413(3)(b), replace "1 March 2026" with "section 398 of the Therapeutic Products Act 2023 commences".

402 Section 420 amended (Pre-commencement legislative requirements: Food Act 1981 and regulations)

In section 420(3)(b), replace "1 March 2026" with "section 398 of the Therapeutic Products Act 2023 commences".

Subpart 3—Amendments to Health Practitioners Competence Assurance Act 2003

403 Principal Act

This subpart amends the Health Practitioners Competence Assurance Act 2003.

404 Section 5 amended (Interpretation)

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

medicinal product means a medicine, as defined in section 22 of the Therapeutic Products Act 2023

prescribe, in relation to a medicinal product, has the same meaning as in section 54 of the Therapeutic Products Act 2023

standing order has the same meaning as in section 55 of the Therapeutic Products Act 2023

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

After section 11(2), insert:

(2A) This section is subject to section 11A(2).

406 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 it does 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 that are 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 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 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).

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

In section 14(1), replace "An" with "Subject to section 14A, an".

408 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 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 power 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 subsections (3) and (5).

(7) In this section, **prescribing provisions** has the same meaning as in section 11A.

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 2023.

(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 2023).

(3) The power of the Minister to delegate under this section—

(a) is subject to any powers, 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.

409 Section 67 amended (Notification of convictions)

(1) Repeal section 67(b)(ix).

(2) After section 67(b)(xi), insert:

(xia) the Pharmacy Ownership Act 1981; or

(3) After section 67(b)(xii), insert:

(xiii) the Therapeutic Products Act 2023.

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

(1) Repeal section 100(2)(a)(ix).

(2) After section 100(2)(a)(xi), insert:

(xia) the Pharmacy Ownership Act 1981; or

(3) After section 100(2)(a)(xii), insert:

(xiia) the Therapeutic Products Act 2023; or

411 Section 170 amended (Regulations)

After section 170(1)(c), insert:

(ca) 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:

412 Schedule 1AA amended

In Schedule 1AA,—

(a) insert the following Part as the last Part; and

(b) make all necessary consequential amendments.

Part 2
Provision relating to Therapeutic Products Act 2023

3 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, on and after the commencement day, 1 or more of the profession's scopes of practice will include the prescribing of medicinal products (as referred to in 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 on reasonable grounds 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 70 of the Therapeutic Products Act 2023 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 2023 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 4—Amendments to Medicines Act 1981

413 Principal Act

This subpart amends the Medicines Act 1981.

414 Long Title repealed

Repeal the Long Title.

415 Section 1 amended (Short Title and commencement)

In section 1(1), replace "Medicines" with "Pharmacy Ownership".

416 Section 2 amended (Interpretation)

(1) In section 2(1), repeal all of the definitions except the definitions of **business**, **dispensing**, **health services**, **hospital**, **pharmacist**, **pharmacy**, **pharmacy practice**, and **sell**.

(2) In section 2(1), insert in its appropriate alphabetical order:

licensing authority means the Therapeutic Products Regulator

(3) In section 2(1), definition of **pharmacy practice**, paragraphs (a) and (c), replace "restricted medicines, or pharmacy-only medicines" with "pharmacist medicines, or pharmacy medicines".

(4) Replace section 2(2) and (3) with:

(2) Terms used in this Act that are not defined in this Act but are defined in the Therapeutic Products Act 2023 have the same meanings in this Act as they have in that Act.

417 Sections 3 to 5A repealed

(1) Repeal sections 3 to 5.

(2) Repeal the section 5A with the heading "**Relationship with Hazardous Substances and New Organisms Act 1996**".

418 Section 5C repealed

Repeal section 5C.

419 Part 1 heading and cross-heading repealed

(1) Repeal the Part 1 heading.

(2) Repeal the cross-heading above section 6.

420 Sections 7 to 16 and cross-heading repealed

Repeal sections 7 to 16 and the cross-heading above section 8.

421 Part 2 heading repealed

Repeal the Part 2 heading.

422 Sections 17 to 42B and cross-headings repealed

Repeal sections 17 to 42B and the cross-headings above sections 24A, 24C, 25, 34A, 35, and 42A.

423 Section 42C amended (Restriction on authorised prescribers and delegated prescribers holding interest in pharmacies)

(1) In the heading to section 42C, replace "**authorised prescribers and delegated prescribers**" with "**health practitioner prescribers**".

(2) In section 42C(1), (2), and (3), replace "authorised prescriber or delegated prescriber" with "health practitioner prescriber".

(3) In section 42C(3), replace "authorised prescriber, or delegated prescriber," with "health practitioner prescriber".

424 Sections 43 to 49A and cross-heading repealed

Repeal sections 43 to 49A and the cross-heading above section 43.

425 Part 3 heading repealed

Repeal the Part 3 heading.

426 Sections 50 to 55C and cross-heading repealed

Repeal sections 50 to 55C and the cross-heading above section 55D.

427 Section 55D amended (Restriction on companies operating pharmacies)

In section 55D(1) and (2), replace "licence to operate a pharmacy" with "pharmacy licence".

428 Section 55E amended (Restriction on individuals operating or holding majority interest in pharmacies)

In section 55E(1), replace "licence to operate a pharmacy" with "pharmacy licence".

429 Part 4 repealed

Repeal Part 4.

430 Part 5 heading repealed

Repeal the Part 5 heading.

431 Sections 63 to 77 repealed

Repeal sections 63 to 77.

432 Sections 79 to 87 repealed

Repeal sections 79 to 87.

433 Parts 6 to 7A repealed

Repeal Parts 6 to 7A.

434 Part 8 heading repealed

Repeal the Part 8 heading.

435 Sections 97 to 104 repealed

Repeal sections 97 to 104.

436 Section 105 amended (Regulations)

(1) Replace section 105(1)(a) to (z) with:

> (a) providing for anything that this Act says must or may be provided for by regulations; and

(2) Repeal section 105(2) to (7).

(3) Repeal section 105(8)(b).

437 Sections 105A and 105B repealed

Repeal sections 105A and 105B.

438 Section 105C amended (Orders in Council providing for exemption from, or modifications of, restrictions on pharmacy ownership and operation)

In section 105C(4), replace "an Internet site maintained by or on behalf of the department" with "the Regulator's website".

439 Sections 105D to 115 repealed

Repeal sections 105D to 115.

440 Schedules 1AA to 3 repealed

Repeal Schedules 1AA to 3.

Subpart 5—Amendments to other legislation

441 Amendments to other legislation

Amend the legislation listed in Schedule 4 as set out in that schedule.

Schedule 1
Transitional, savings, and related provisions

s 5

Contents

Part 1
Provisions relating to this Act as enacted

1 Interpretation for this Part

(1) In this Part of this schedule, unless the context otherwise requires,—

1981 Act means the Medicines Act 1981 as in force before commencement and any regulations and other instruments made under it

applicant, in relation to an application made under the 1981 Act, means the person in whose name the application was made

commencement means when this clause comes into force

existing notice means a notice issued under the 1981 Act that is in effect immediately before commencement

existing provisional consent means a provisional consent under section 23 of the 1981 Act that is in effect immediately before commencement

existing standard consent means either of the following that is in effect immediately before commencement:

(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 consent under section 24(3) of the 1981 Act

new provisional consent means either of the following:

(a) a consent given under clause 13, 15, or 17 of this schedule in relation to an application made under section 23 of the 1981 Act:

(b) a consent that is taken to have been given under clause 4 of this schedule for a medicine, if the unchanged medicine had a provisional consent under section 23 of the 1981 Act

new standard consent means either of the following:

(a) a consent given under clause 13, 15, or 17 of this schedule in relation to an application made under section 20 of the 1981 Act:

(b) a consent that is taken to have been given under clause 4 of this schedule for a medicine, if the unchanged medicine had an existing standard consent

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 of this schedule, but not defined in this Act, has the same meaning as in the 1981 Act.

(3) If a provision of this Part of this schedule requires or allows the Regulator to do something as if the 1981 Act and not this Act were in force, the 1981 Act applies as if all references to the Minister or Director-General were references to the Regulator and with any other necessary modifications.

Subpart 1—Market authorisations

Consents under 1981 Act

2 Standard consent becomes standard authorisation

(1) This clause applies to a therapeutic product that was, immediately before commencement, a medicine under the 1981 Act and is a medicine under this Act.

(2) If the medicine has an existing standard consent, on commencement it becomes a standard authorisation for the medicine.

(3) If a new standard consent is given for the medicine, it becomes a standard authorisation for the medicine immediately after the consent is given or taken to have been given.

(4) A standard authorisation created by this clause—

(a) applies to the medicine as described in the consent; and

(b) authorises the medicine for the purposes or indications described in the consent; and

(c) is taken to have been issued to the applicant for the consent (who is therefore the sponsor of the medicine); and

(d) has the same expiry date (if any) as the consent had (or, for a new standard consent, would have had) under the 1981 Act; and

(e) is subject to all of the conditions (whether relating to the medicine or the sponsor) to which the consent was (or, for a new standard consent, would have been) subject under the 1981 Act.

(5) However, this clause does not apply to a product that was a medicine under the 1981 Act but is now—

(a) a medical device under this Act (*see instead* clause 5 of this schedule); or

(b) an NHP under this Act (*see instead* clause 6 of this schedule).

Guidance note

For a medicine grandfathered under the Food and Drugs Act 1947, *see* clause 9 of this schedule.

3 Provisional consent becomes provisional authorisation

(1) This clause applies to a therapeutic product that was, immediately before commencement, a medicine under the 1981 Act and is a medicine under this Act.

(2) If the medicine has an existing provisional consent, on commencement it becomes a provisional authorisation for the medicine.

(3) If a new provisional consent is given for the medicine, it becomes a provisional authorisation for the medicine immediately after it is given or taken to have been given.

(4) A provisional authorisation created by this clause—

(a) applies to the medicine as described in the consent; and

(b) authorises the medicine for the purposes or indications described in the consent; and

(c) is taken to have been issued to the applicant for the consent (who is therefore the sponsor of the medicine); and

(d) expires 2 years after commencement; and

(e) is subject to all of the conditions (whether relating to the medicine or the sponsor) to which the consent was (or, for a new provisional consent, would have been) subject under the 1981 Act.

(5) However, this clause does not apply to a product that was a medicine under the 1981 Act but is now—

(a) a medical device under this Act (*see instead* clause 5 of this schedule); or

(b) an NHP under this Act (*see instead* clause 6 of this schedule).

4 Existing changed medicine notice: 1981 Act continues to apply for 90-day period

(1) This clause applies if,—

(a) before commencement, a notice was deposited under section 24(1) of the 1981 Act in relation to a changed medicine; and

(b) as at commencement, the 90-day period referred to in section 24(3) of the 1981 Act has not expired.

(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.

(3) If the Regulator forms an opinion referred to in section 24(5) of the 1981 Act within the 90-day period, then, on the expiry of the 90-day period,—

(a) the 1981 Act ceases to apply to the matter; and

(b) the changed medicine becomes a medicine that does not have a market authorisation (and this Act, including any other applicable provisions of this schedule, applies accordingly).

(4) If the Regulator does not form that opinion, they are taken to have given consent for the changed medicine at the expiry of the 90-day period.

(5) This clause does not affect the authorisation created by clause 2 or 3 of this schedule for the unchanged medicine.

Guidance note

A consent that is taken to have been given under subclause (4) becomes a market authorisation under clause 2, 3, or 5 of this schedule.

See clause 1(3) in relation to the Regulator acting under the 1981 Act.

5 Product that was medicine but is now medical device: consent becomes temporary market authorisation

(1) This clause applies to a therapeutic product that was, immediately before commencement, a medicine under the 1981 Act but is now a medical device under this Act.

(2) If the product has an existing standard consent or existing provisional consent, on commencement it becomes a temporary market authorisation for the product as a medical device.

(3) If a new standard consent or new provisional consent is given for the product, it becomes a temporary market authorisation for the product as a medical device immediately after the consent is given or taken to have been given.

(4) A temporary market authorisation created by this clause—

(a) applies to the product as described in the consent; and

(b) is taken to have been issued to the applicant for the consent (who is therefore the sponsor of the device); and

(c) expires 5 years after commencement; and

(d) is subject to all of the conditions (whether relating to the product or the sponsor) to which the consent was (or, for a new standard consent or new provisional consent, would have been) subject under the 1981 Act.

Guidance note

If an application for a market authorisation is made before the temporary market authorisation expires, the duration of the temporary market authorisation may be extended under clause 19 of this schedule.

6 Product that was consented medicine but is now NHP: deemed to be medicine

(1) This clause applies to a therapeutic product that,—

(a) immediately before commencement, was a medicine under the 1981 Act but is now an NHP under this Act; and

(b) has an existing standard consent or existing provisional consent.

(2) On commencement,—

(a) the product becomes a medicine as if the Regulator had made a Regulator's notice under section 21(5) of this Act saying that the product is a medicine; and

(b) clause 2 or 3 of this schedule (as the case requires) applies.

Guidance note

For all other NHPs, see clause 12 of this schedule.

7 Emergency approval becomes provisional authorisation

(1) If, immediately before commencement, there is an emergency approval in force for a medicine, on commencement it becomes a provisional authorisation for the medicine.

(2) If an emergency approval is granted under clause 17 of this schedule for a medicine, it becomes a provisional authorisation for the medicine immediately after it is granted.

(3) A provisional authorisation created by this clause—

(a) applies to the medicine as described in the emergency approval; and

(b) authorises the medicine for the purposes or indications described in the emergency approval; and

(c) is taken to have been issued to the applicant for the emergency approval (who is therefore the sponsor of the medicine); and

(d) has the same expiry date as the emergency approval had (or, for an approval referred to in subclause (2), would have had) under the 1981 Act; and

(e) is subject to all of the conditions (whether relating to the medicine or the sponsor) to which the emergency approval was (or, for an approval referred to in subclause (2), would have been) subject under the 1981 Act.

(4) In this clause, **emergency approval** means an approval for a medicine under section 24D of the 1981 Act.

8 Related product under Part 7 of 1981 Act that is now therapeutic product

(1) This clause applies to a therapeutic product that,—

(a) immediately before commencement, was a related product as defined in section 94 of the 1981 Act; and

(b) is now a therapeutic product under this Act.

(2) This Part of this schedule applies to the product and any application, notice, or consent relating to it, as if—

(a) the references in those clauses to provisions of the 1981 Act were references to those provisions as applied by section 96 of the 1981 Act; and

(b) the product had been a medicine under the 1981 Act.

Products not required to have consent under 1981 Act

9 Medicine grandfathered under Food and Drugs Act 1947: temporary market authorisation created

(1) This clause applies to a medicine that, immediately before commencement, 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) On commencement, a temporary market authorisation is created for the medicine.

(3) A temporary market authorisation created by this clause—

(a) applies to the medicine as it would have been described in a market authorisation issued for it on commencement (had that happened); and

(b) authorises the import, export, or supply of the medicine to the extent that it was lawful immediately before commencement; and

(c) is taken to have been issued to the responsible manufacturer (who is therefore the sponsor of the medicine); and

(d) expires 3 months after commencement.

(4) However, if the sponsor notifies the Regulator of the name, dose form, active ingredients, strength, and responsible manufacturer of the medicine before the expiry of that 3-month period, the authorisation created by this clause continues in force until the expiry of 12 months after commencement.

Guidance note

If an application for a market authorisation is made before the temporary market authorisation expires, the duration of the temporary market authorisation may be extended under clause 19 of this schedule.

10 Medical devices listed under 1981 Act: temporary market authorisation created

(1) This clause applies to a medical device that, immediately before commencement,—

(a) was a medical device under the 1981 Act; and

(b) was not an exempt medical device under the Medicines (Database of Medical Devices) Regulations 2003; and

(c) was lawfully being imported into, supplied in, or exported from New Zealand.

(2) On commencement, a temporary market authorisation is created for the device.

(3) A temporary market authorisation created by this clause—

(a) applies to the device as it would have been described in a market authorisation issued for it on commencement (had that happened); and

(b) authorises the device for the purposes or indications for which it was lawfully being used immediately before commencement; and

(c) is taken to have been issued to the following person (who is therefore the sponsor of the device):

(i) if the responsible manufacturer meets the criterion in section 124(1)(a) of this Act, that person; or

(ii) if subparagraph (i) does not apply but another manufacturer meets that criterion, that person; or

(iii) if neither subparagraph (i) nor (ii) applies, the importer of the device; and

(d) expires,—

(i) if the device was classified as a Class III or Class AIMD medical device under the Medicines (Database of Medical Devices) Regulations 2003, 3 years after commencement; or

(ii) otherwise, 5 years after commencement.

Guidance note

If an application for a market authorisation is made before the temporary market authorisation expires, the duration of the temporary market authorisation may be extended under clause 19 of this schedule.

11 Unlisted medical device or unregulated product that is now medicine or medical device: temporary market authorisation created

(1) This clause applies to a therapeutic product that,—

(a) immediately before commencement,—

(i) was a medical device under the 1981 Act but was an exempt medical device under the Medicines (Database of Medical Devices) Regulations 2003; or

(ii) was not a medicine or medical device under the 1981 Act; and

(b) is now a medicine or medical device under this Act; and

(c) was lawfully being imported into, supplied in, or exported from New Zealand immediately before commencement.

(2) On commencement, a temporary market authorisation is created for the medicine or medical device.

(3) A temporary market authorisation created by this clause—

(a) applies to the product as it would have been described in a market authorisation issued for it on commencement (had that happened); and

(b) authorises the product for the purposes or indications for which it was lawfully being used immediately before commencement; and

(c) is taken to have been issued to the following person (who is therefore the sponsor of the device):

(i) if the responsible manufacturer meets the criterion in section 124(1)(a) of this Act, that person; or

(ii) if subparagraph (i) does not apply but another manufacturer meets that criterion, that person; or

(iii) if neither subparagraph (i) nor (ii) applies, the importer of the device; and

(d) expires 6 months after commencement.

Guidance note

If an application for a market authorisation is made before the temporary market authorisation expires, the duration of the temporary market authorisation may be extended under clause 19 of this schedule.

12 NHPs: temporary market authorisation created

(1) This clause applies to an NHP that,—

(a) immediately before commencement, was lawfully being imported into, supplied in, or exported from New Zealand in the course of a business or undertaking; and

(b) is not a low-concentration NHP.

(2) On commencement, a temporary market authorisation is created for the product.

(3) A temporary market authorisation created by this clause—

(a) applies to the NHP as it would have been described in a market authorisation issued for it on commencement (had that happened); and

(b) permits the sponsor to make the health benefit claims about it that were lawfully being made immediately before commencement; and

(c) is taken to have been issued to the following person (who is therefore the sponsor of the device):

(i) if the responsible manufacturer meets the criterion in section 128(1)(a) of this Act, that person; or

(ii) if subparagraph (i) does not apply but another manufacturer does meet that criterion, that person; or

(iii) if neither subparagraph (i) nor (ii) applies, the importer of the device; and

(d) expires 2 years after commencement.

(4) This clause does not apply to a product that was a medicine under the 1981 Act with an existing standard consent or an existing provisional consent (*see instead* clause 6 of this schedule).

Guidance note

This clause does not apply to low-concentration NHPs because they are not required to have a market authorisation (*see* section 68 of this Act).

Pending applications for consent under 1981 Act

13 Pending application for consent dealt with as under 1981 Act

(1) This clause applies to a 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.

(3) However, this clause is subject to clauses 14 to 16 and 18 of this schedule.

Guidance note

A consent given under this clause becomes a market authorisation under clause 2, 3, or 5 of this schedule.

See clause 1(3) in relation to the Regulator acting under the 1981 Act.

14 Power to lapse pending application

(1) This clause applies to a pending application referred to in clause 13 of this schedule—

(a) if, on an initial evaluation of the application, the Regulator thinks that it is substantially deficient; or

(b) if,—

(i) before commencement, the Director-General issued a requirement under section 21(4) or (5) of the 1981 Act; and

(ii) 12 months have elapsed since it was issued; and

(iii) the applicant has not complied with it; or

(c) if,—

(i) after commencement, the Regulator—

(A) issues a requirement under section 21(4) or (5) of the 1981 Act; and

(B) advises the applicant of the consequences of not complying with it; and

(ii) 6 months have elapsed since it was issued; and

(iii) the applicant has not complied with it.

(2) The Regulator may treat the application as lapsed and must inform the applicant accordingly.

(3) The Regulator need not refund any fee paid under the 1981 Act or this Act in relation to the application.

15 Pending application if matter before appropriate committee

(1) This clause applies to a pending application referred to in clause 13 of this schedule if,—

(a) before commencement, the Minister referred the application to the appropriate committee under section 22(2) of the 1981 Act; but

(b) as at commencement, that committee had not reported on the matter with a recommendation as to the decision that the Minister should make.

(2) The Regulator may ask the committee to continue considering the matter and advise the Regulator on the decision under the 1981 Act that the Regulator should make (in which case the committee is continued in existence for that purpose as if the 1981 Act, and not this Act, were in force).

(3) The Regulator must otherwise consider and determine the application as if the 1981 Act, and not this Act, were in force (but without the need for a report from the committee if the committee is not continued under subclause (2)).

Guidance note

A consent given under this clause becomes a market authorisation under clause 2, 3, or 5 of this schedule.

See clause 1(3) in relation to the Regulator acting under the 1981 Act.

16 Pending application if objection before Medicines Review Committee

(1) This clause applies to a pending application referred to in clause 13 of this schedule if,—

(a) before commencement, the Minister referred an objection to the Medicines Review Committee under section 22(5) of the 1981 Act; and

(b) as at commencement, the committee had not reported 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 373 of this Act; and

(b) the panel must review the matter and make a decision under section 375 of this Act but as if the 1981 Act, and not this Act, were in force; and

(c) the Regulator must otherwise consider and determine the application as if the 1981 Act, and not this Act, were in force.

Guidance note

A consent given under this clause becomes a market authorisation under clause 2, 3, or 5 of this schedule.

See clause 1(3) in relation to the Regulator acting under the 1981 Act.

17 Pending application for emergency approval

(1) This clause applies to a pending application for approval to distribute, sell, or advertise a medicine in a special emergency that was made under section 24D of the 1981 Act.

(2) The Regulator may consider and determine the application, and give approval or not, as if the 1981 Act, and not this Act, were in force.

Guidance note

See clause 1(3) in relation to the Regulator acting under the 1981 Act.

18 Pending application if product contains new organism: approval under Hazardous Substances and New Organisms Act 1996

(1) This clause applies to a pending application referred to in clause 13 or 17 of this schedule if—

(a) it relates to a qualifying new medicine as defined in section 2 of the 1981 Act; and

(b) 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; and

(c) immediately before commencement, there was in force a delegation referred to in section 24A of the 1981 Act that would have allowed the Director-General to grant an approval under section 38I of the Hazardous Substances and New Organisms Act 1996 for the release of the medicine; and

(d) either—

(i) a consent is given under clause 13, 15, or 16 of this schedule; or

(ii) approval is given under clause 17 of this schedule.

(2) The Regulator may grant an approval under section 38I of the Hazardous Substances and New Organisms Act 1996 for the release of the medicine as if the Regulator were the delegate under that delegation.

(3) If the Regulator declines to grant approval under section 38I of that Act 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.

Guidance note

See clause 1(3) in relation to the Regulator acting under the 1981 Act.

General provisions for all market authorisations created by this Part

19 Duration of temporary market authorisation

(1) This clause applies if a temporary market authorisation for a product is created by a provision of this Part of this schedule (other than clause 12).

(2) If an application is made under Part 4 of this Act for a market authorisation for the product before the temporary market authorisation expires, the temporary market authorisation continues in force until the Regulator determines the application.

(3) The Regulator may exercise their power under section 138 of this Act to vary the temporary market authorisation so that it expires earlier than it otherwise would.

20 Sponsor to notify Regulator of relationship with responsible manufacturer

(1) This clause applies if,—

(a) under this Part of this schedule,—

(i) a consent under the 1981 Act for a medicine becomes a standard authorisation or provisional authorisation; or

(ii) a temporary market authorisation is created for a therapeutic product; and

(b) the person who becomes the sponsor is not the responsible manufacturer of the product.

(2) It is a condition of the market authorisation that the sponsor must, within 6 months after commencement, give the Regulator a statutory declaration that the person has a contractual relationship with the responsible manufacturer that meets the criterion in section 124(2) or 128(2) of this Act.

21 Market authorisation created by this Part but product has no sponsor

(1) This clause applies if,—

(a) under this Part of this schedule,—

(i) a consent under the 1981 Act for a medicine becomes a standard authorisation or provisional authorisation; or

(ii) a temporary market authorisation is created for a therapeutic product; and

(b) the person who would become the sponsor of the product does not exist (for example, because they have died or been wound up).

(2) The market authorisation subsists even though there is no sponsor.

(3) The Regulator may exercise their power under section 133 of this Act to transfer the market authorisation to a new sponsor on application by a proposed new sponsor.

(4) If an application to transfer is made within 1 year of commencement,—

(a) the market authorisation remains in force until the Regulator determines the application; and

(b) until the application is determined, the applicant is taken to be the sponsor.

(5) If no application is made within 1 year of commencement, the market authorisation expires.

Subpart 2—Licences

Existing licences under 1981 Act

22 Existing licence continues

(1) On commencement, an existing licence of a kind listed in the following table becomes a licence under this Act of the kind listed in the table:

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

(2) A licence created by subclause (1) has all of the same terms and conditions, and the same expiry date, as the existing licence.

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

(4) In this clause, **existing licence** means a licence under Part 3 of the 1981 Act that is in effect immediately before commencement.

Pending applications for licences, etc.

23 Pending application for licence dealt with under this Act

(1) This clause applies to a pending application for a licence under Part 3 of the 1981 Act.

(2) The Regulator may consider and determine a pending application of a kind listed in the following table as if it were an application made under this Act of the kind listed in 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 therapeutic products
Application for a licence to hawk medicines	The application lapses (*see* clause 24 of this schedule)
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 therapeutic products
Application for a licence to sell pharmacy-only medicines by retail	As an application for a licence for non-wholesale supply of therapeutic products

Pending applications under 1981 Act	How considered and determined under this Act
Application for a licence to pack or label medicines	As an application for a licence to manufacture therapeutic products
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 of this schedule.

24 Pending application to hawk medicine lapses

(1) This clause applies to a 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 applicant what needs to be done to deal with the matter under this Act; and

(b) refund any fee paid under the 1981 Act.

25 Pending application for approval to conduct clinical trial dealt with as application for licence

(1) This clause applies to a pending application for approval to conduct a clinical trial made under section 30 of the 1981 Act.

(2) The Regulator may consider and determine the application as if it were an application made under Part 5 of this Act for a licence to conduct a clinical trial.

Biotechnical procedures (xenotransplantation) under Part 7A of 1981 Act

26 Treatment of pending applications dealt with as application for licence to administer medicine or use device

(1) This clause applies to a pending application that was made under Part 7A of the 1981 Act.

(2) The Regulator may consider and determine the application as if it were an application under Part 5 of this Act for a licence to administer a medicine or use a medical device that is or contains the biological material to which the application relates.

Licences relating to existing devices

27 Licences for activities with medical device, or product not regulated, under 1981 Act

(1) This clause applies to a person who was, immediately before commencement, manufacturing, supplying, or exporting—

(a) a medical device to which clause 10 of this schedule applies; or

(b) a medicine or medical device to which clause 11 of this schedule applies.

(2) On commencement, a licence is created with that person as the licensee.

(3) The licence allows the licensee to continue manufacturing, supplying, or exporting the product, and doing anything related to doing so, in the same way as they were lawfully doing immediately before commencement.

(4) However, if, immediately before commencement, the product was a sunscreen product (as defined in section 3 of the Sunscreen (Product Safety Standard) Act 2022), this clause applies only if the person continues to comply with that Act as if it were still in force.

(5) The licence expires 12 months after commencement.

Licences relating to existing NHPs

28 Licences created in relation to controlled activities with NHP

(1) This clause applies to a person who was, immediately before commencement, carrying on an activity that is now a controlled activity with an NHP.

(2) On commencement, a licence is created with that person as the licensee.

(3) The licence allows the licensee to continue carrying on that activity, and continue doing anything related to doing so, in the same way as they were lawfully doing immediately before commencement.

(4) However, if, immediately before commencement, the product was a food (as defined in section 9 of the Food Act 2014), this clause applies only if the person continues to comply with that Act as if the product were still a food.

(5) The licence expires 2 years after commencement.

Existing clinical trials

29 12-month licence for existing approved clinical trials

(1) This clause applies to a clinical trial if, immediately before commencement,—

(a) the trial was lawfully being conducted; and

(b) the clinical trial and the persons (the **investigators**) conducting it had an approval given by the Director-General on the recommendation of the Health Research Council of New Zealand under section 30 of the 1981 Act.

(2) On commencement, a licence is created for the clinical trial.

(3) The licence—

(a) is taken to have been issued to the person who made the application under section 30 of the 1981 Act (who is therefore the licensee); and

(b) authorises the investigators to conduct the trial, and carry on related supply chain activities, to the extent that they were lawfully doing so in New Zealand immediately before commencement; and

(c) expires 12 months after commencement; and

(d) otherwise has all of the same terms and conditions as applied to the conduct of the trial immediately before commencement.

(4) However, if the licensee applies under Part 5 of this Act for a licence for the clinical trial before the licence created by subclause (2) expires, that licence continues in force until the Regulator determines the application.

30 6-month licence for existing unapproved clinical trials

(1) This clause applies to a clinical trial if, immediately before commencement,—

(a) the trial was lawfully being conducted; and

(b) the clinical trial and the persons (the **investigators**) conducting it did not have an approval given by the Director-General on the recommendation of the Health Research Council of New Zealand under section 30 of the 1981 Act.

(2) On commencement, a licence is created for the clinical trial.

(3) The licence—

(a) is taken to have been issued to the person primarily responsible for the management or conduct of the trial (who is therefore the licensee); and

(b) authorises the investigators to conduct the trial, and carry on related supply chain activities, to the extent that they were lawfully doing so in New Zealand immediately before commencement; and

(c) expires 6 months after commencement; and

(d) otherwise has all of the same terms and conditions as applied to the conduct of the trial immediately before commencement.

(4) However, if the licensee applies under Part 5 of this Act for a licence for the clinical trial before the licence created by subclause (2) expires, that licence continues in force until the Regulator determines the application.

Subpart 3—Other matters under 1981 Act continued

31 Classes of medicines

(1) This clause applies to a medicine that was lawfully being supplied immediately before commencement.

(2) On commencement, a medicine with a classification under the 1981 Act listed in the following table becomes a medicine in the class under this Act listed in the table:

Classification under 1981 Act	Class under this Act
Prescription medicine	Prescription medicine
Restricted medicine	Pharmacist medicine
Pharmacy-only medicine	Pharmacy medicine
Medicine not classified as a prescription medicine, restricted medicine, or pharmacy-only medicine	General-sale medicine

Exemptions under sections 25 and 29 of 1981 Act

32 6-month grace period for authorised prescribers and others

(1) This clause applies to a person who was, immediately before commencement, authorised—

(a) under section 25 of the 1981 Act to do any of the things set out in section 25(1)(a), (d), or (e) of that Act; or

(b) under section 29 of the 1981 Act to supply or administer a medicine.

(2) After commencement, the person is allowed to continue to do those things as if the 1981 Act, and not this Act, were in force.

(3) However, the person is subject to all of the conditions and requirements that applied to them under the 1981 Act.

(4) This clause ceases to apply 6 months after commencement.

Prescriptions and standing orders

33 Prescription continues

(1) On commencement, a prescription that was validly issued under the 1981 Act (or to the extent that it was validly issued), and was in effect immediately before commencement, becomes a complying prescription.

(2) It remains a complying prescription until it expires under section 54 of this Act.

34 Standing order continues

(1) On commencement, a standing order that was validly issued under the 1981 Act (or to the extent that it was validly issued), and was in effect immediately before commencement, becomes a complying standing order.

(2) It remains a complying standing order for 2 years after commencement unless, before then, it ceases to be in force under section 55(3) of this Act.

Innovative medicine application protection periods

35 Innovative medicine application protection periods continue uninterrupted

(1) This clause applies for the purpose of determining whether an application for a market authorisation for a medicine (**medicine A**) made under this Act by a person (**person A**) is an innovative medicine application (as defined in section 151 of this Act).

(2) In paragraph (b) of the definition of **innovative medicine application**, the reference to an application for a market authorisation for a medicine—

(a) includes either of the following:

(i) an application for the consent of the Minister under section 20 of the 1981 Act in relation to a medicine:

(ii) an application for the provisional consent of the Minister under section 23 of the 1981 Act in relation to a medicine; but

(b) does not include an application made by person A for provisional consent in relation to medicine A.

Pending appeals to Medicines Review Committee

36 Pending appeal against decision to refuse licence dealt with by review panel

(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 373 of this Act; and

(b) the panel must review the matter and notify the Regulator of its decision under section 375 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.

Guidance note

See clause 1(3) in relation to the Regulator acting under the 1981 Act.

Other notices under 1981 Act

37 Existing notice under section 36 of 1981 Act continues as requirement to give information or directions order

(1) On commencement, an existing notice issued under section 36(1) of the 1981 Act becomes a notice under section 209 of this Act with a requirement that the person to whom it was given must comply with it within 60 days after the notice was given.

(2) On commencement, an existing notice issued under section 36(3) of the 1981 Act becomes a directions order under section 223 of this Act that expires 12 months after commencement (or on any earlier date specified in the notice).

38 Existing notice under section 37 of 1981 Act continues as product moratorium order

On commencement, an existing notice issued under section 37 of the 1981 Act becomes a product moratorium order under section 225 of this Act that expires 12 months after commencement (or on any earlier date specified in the notice).

39 Existing notice under section 38 of 1981 Act continues as requirement to give information or directions order

(1) This clause applies to an existing notice issued under section 38(2) or (4) of the 1981 Act in relation to a medical device.

(2) If the 45-day period in section 38(3) or (4) of the 1981 Act expired before commencement, on commencement the existing notice becomes a directions order under section 223 of this Act that—

(a) prohibits the person who was given the notice from supplying the device; and

(b) expires 12 months after commencement (or on any earlier date specified in the notice).

(3) If the 45-day period had not expired before commencement, on commencement the existing notice becomes a notice under section 209 of this Act requiring the person who was given the notice to comply with it within 45 days after it was given.

Subpart 4—Miscellaneous transitional provisions

40 Application of Act to things to which this Part applies

(1) A market authorisation, licence, or permit created by, or issued or granted under, this Part of this schedule (including any regulations made under clause 45) has effect—

(a) as if it had been issued or granted under the relevant provision of this Act; and

(b) as if the criteria for issuing or granting it were, at commencement, met by the circumstances that existed at that time; and

(c) as if any other preconditions for issuing or granting it had been met at commencement; and

(d) in the case of a temporary market authorisation, as if it were a standard authorisation but for a fixed period.

(2) This Act applies to the market authorisation, licence, or permit accordingly.

(3) This Act applies to any person who, after commencement, carries on a supply chain activity with, or does anything else in relation to, a therapeutic product to which this Part of this schedule applies.

(4) The Regulator, and any other person with functions or powers under this Act, may perform all of their functions and exercise all of their powers in relation to a product, person, market authorisation, licence, permit, or other thing to which this Part of this schedule applies.

(5) However, this clause is subject to the rest of this Part (including any regulations made under clause 45).

Example

A temporary market authorisation for a medical device created by clause 10 would have effect as if—

(a) the manufacturer (or other person referred to in clause 10(3)(c)) had applied for a market authorisation in accordance with section 121; and

(b) the Regulator had, at commencement,—

(i) determined that the device's safety, quality, and performance for its intended authorised indications were, at that time, satisfactorily established; and

(ii) been satisfied that, at that time, all of the other criteria for a standard authorisation were met; and

(c) the authorisation had been issued by the Regulator under section 121.

If, after commencement, a new risk emerges in relation to the device (such as previously unknown serious side effects), the Regulator could take the same actions in relation to the device as they could take for a device that has a market authorisation issued under section 121. That might include requiring the sponsor to provide more information, making regulatory orders, and varying or cancelling the market authorisation if grounds exist.

Fees

41 Transitional evaluation fee for pending application for consent

(1) This clause applies to a pending application referred to in clause 13 of this schedule if—

(a) the application was made after the date on which this Act receives Royal assent but before commencement; and

(b) as at commencement, evaluation work has not started.

(2) This clause also applies, with any necessary modifications, to a pending application referred to in clause 17 of this schedule.

(3) In this clause, **evaluation work** means either or both of the following:

(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.

42 Fees for existing application or proceeding

(1) This clause applies if a pending application or proceeding is to be considered or determined under this Act by reason of this Part of this schedule.

(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 person who would be liable to pay the fee if the application, proceeding, or other matter had started under this Act.

(3) The Regulator may defer dealing with the application, proceeding, or other matter until that fee is paid.

(4) This clause does not limit clause 41 of this schedule.

Guidance note

No fee is payable in respect of the creation of a market authorisation, licence, permit, or other authorisation that is created by this Part of this schedule.

Regulator's powers

43 Principles guiding exercise of powers include orderly transition to this Act

The principles set out in section 4 of this Act are taken to include that there should be an orderly transition to this Act.

44 New regulatory and investigative powers and administrative provisions apply to matters under this Part

(1) Sections 201 to 204, subpart 2 of Part 7, subpart 1 of Part 8, and subparts 4 and 6 of Part 9 of this Act (which relate to regulatory and investigative powers, administrative matters, etc) apply after commencement—

(a) when any pending application, proceeding, or other matter is considered or determined under this Part of this schedule; and

(b) for the purpose of commencing or continuing any enforcement action in respect of a contravention of the 1981 Act.

(2) For the purposes of subpart 6 of Part 9 as applied by subclause (1), the provision of this schedule under which a decision referred to in subclause (1)(a) is made is taken to be listed in Schedule 3.

(3) Subclause (1) applies regardless of whether the 1981 Act or this Act applies to the matter after commencement under this Part of this schedule.

Regulations

45 Transitional regulations

(1) The regulations may provide for transitional and savings matters concerning the coming into force of this Act.

(2) The regulations—

(a) may be in addition to, or in place of, the provisions in this Part of this schedule; and

(b) may extend any transitional period specified in this Part of this schedule.

(3) However, the expiry date of any transitional period extended under subclause (2)(b) cannot be later than,—

(a) in the case of a period within which a person may apply for a market authorisation, licence, or permit, 3 years after commencement; and

(b) in any other case, when this clause is repealed by subclause (6).

(4) The regulations may provide that, during a specified transitional period, either or both of the following are the case:

(a) that specified provisions of this Act do not apply or apply with modifications:

(b) that the 1981 Act or specified provisions of that Act continue to apply (with or without modifications).

(5) The Minister must not recommend that regulations be made for the purposes of this clause unless satisfied on reasonable grounds that they are necessary to facilitate an orderly transition from the regulatory regime that existed before commencement to the regime established by this Act.

(6) This clause is repealed, and any regulations made in reliance on it are revoked, 5 years after commencement.

Schedule 2
Crown-enforceable offences and Crown-enforceable infringement offences

ss 304, 305

Provision contravened	Crown-enforceable offence	Crown-enforceable infringement offence
s 68 (market authorisation required to import, supply, or export)	✓	✓
s 69 (sponsor's consent required to import product with standard authorisation or provisional authorisation)	✓	✓
s 70 (controlled activity prohibited unless allowed by licence, permit, or subpart 3)	✓	✓
s 71 (non-wholesale supply of prescription medicine: prescription required)	✓	
s 73 (person in supply chain must comply with rules)	✓	✓
s 74 (person in supply chain must comply with qualification, training, and competency requirements)	✓	✓
s 75 (prohibited products)	✓	
s 142 (sponsor must ensure compliance with market authorisation)	✓	✓
s 143 (sponsor must ensure product meets product standards)	✓	✓
s 144 (sponsor must ensure product meets export standards)	✓	✓
s 145 (sponsor must have surveillance and response system)	✓	✓
s 146 (sponsor must comply with rules)	✓	✓
s 147 (sponsor must notify Regulator of certain minor changes)	✓	✓
s 148 (sponsor of reportable product must notify Regulator of likely shortage)		✓
s 149 (sponsor of reportable product must notify decision to stop supplying product)		✓
s 183 (licensee or permit holder must ensure health practitioner or veterinarian has authority and resources)	✓	
s 184 (licensee, permit holder, or senior manager must not induce health practitioner or veterinarian to act unprofessionally)	✓	
s 185 (licensee and permit holder must comply with qualification, training, and competency requirements)	✓	
s 187 (protection of responsible person from retaliation)	✓	
s 188 (responsible person must comply with rules)		✓
s 189 (pharmacy licensee must ensure pharmacy activities are carried on by persons allowed to do so)	✓	✓
s 190 (tampering with therapeutic products)	✓	
s 191 (supply chain activity with tampered-with products)	✓	
s 192 (notifying Regulator of suspicion of tampering)	✓	✓

Provision contravened	Crown-enforceable offence	Crown-enforceable infringement offence
s 193 (misrepresentation about therapeutic product)	✓	✓
s 199 (agreeing or offering to carry on supply chain activity unlawfully)		✓
s 201 (misleading information in records)	✓	✓
s 202 (misleading information to Regulator or inspector)	✓	✓
s 203(1) (compliance with regulatory or investigative requirement)	✓	✓
s 204 (obstructing Regulator or inspector)	✓	
s 218 (compliance with recall order)	✓	
s 220 (compliance with premises restriction order)	✓	
s 224 (compliance with directions order)	✓	
s 226 (compliance with product moratorium order)	✓	✓
s 228 (compliance with prohibited product order)	✓	✓
s 231 (compliance with medicine access limitation order)	✓	✓
s 299 (compliance with enforceable undertaking)	✓	
s 352 (information not to be disclosed)	✓	

Schedule 3
Reviewable decisions

s 372

Section	Description	Who may apply for review
	NHPs	
s 21(5)	Notice that NHP is a medicine	Applicant
s 63	Amendment of rules setting out standard health benefit claims	Applicant
	Market authorisations	
s 121	Application and issue of market authorisation for medicine or medical device	Applicant
s 126	Issue of market authorisation for NHP	Applicant
s 133	Change of sponsor	Sponsor
s 136	Conditions on market authorisation	Applicant or sponsor
s 137	Variation of market authorisation on application by sponsor	Sponsor
s 138	Variation of market authorisation by Regulator	Sponsor
s 140	Regulator may cancel market authorisation if grounds exist	Sponsor
s 141	Regulator may cancel market authorisation on application	Sponsor
	Licences and permits	
s 159	Grant of licence	Applicant
s 167	Grant of permit	Applicant
s 170	Conditions on licence or permit	Licensee or permit holder
s 171	Variation of licence or permit	Licensee or permit holder
s 174	Regulator may suspend or cancel if grounds exist	Licensee or permit holder
s 176	Regulator may suspend or cancel on application	Licensee or permit holder
s 178	Lifting of suspension	Licensee or permit holder
	Regulatory powers	
s 237	Variation of regulatory order	Applicant
s 238	Revocation of regulatory order	Applicant
s 240	Official statement for export of therapeutic product	Applicant

Schedule 4
Amendments to other Acts

s 441

Accident Compensation Act 2001 (2001 No 49)

In section 6(1), definition of **pharmaceutical**, replace paragraph (a) with:

(a) a prescription medicine, pharmacist medicine, or pharmacy medicine (as defined in section 14 of the Therapeutic Products Act 2023); or

In Schedule 1, replace clause 3(1)(c) with:

(c) pharmaceuticals supplied, prescribed, or administered by a treatment provider who is allowed to do so under the Therapeutic Products Act 2023:

Agricultural Compounds and Veterinary Medicines Act 1997 (1997 No 87)

In section 4A(5), replace "Medicines Act 1981" with "Therapeutic Products Act 2023".

Replace section 21(4) with:

(4) If the application relates to a trade name product that is a prescription medicine (as defined in section 14 of the Therapeutic Products Act 2023), the Director-General must not grant the application without the consent of the Regulator (as defined in that Act).

Replace section 79(c) with:

(c) Therapeutic Products Act 2023:

Animal Products Act 1999 (1999 No 93)

Replace section 161(5)(a)(vii) with:

(vii) the Therapeutic Products Act 2023:

Animal Welfare Act 1999 (1999 No 142)

In section 2(1), definition of **cosmetic**, replace paragraph (c)(i), (ii), (iii), and (vi) with:

(i) a therapeutic product, as defined in section 16 of the Therapeutic Products Act 2023; or

In section 2(1), replace the definition of **substance** with:

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

Biosecurity Act 1993 (1993 No 95)

Replace section 117A(2)(g) with:

(g) the Therapeutic Products Act 2023:

Contraception, Sterilisation, and Abortion Act 1977 (1977 No 112)

Repeal section 6.

Contract and Commercial Law Act 2017 (2017 No 5)

In Schedule 5, Part 2, repeal the item relating to the Medicines Regulations 1984.

Copyright Act 1994 (1994 No 143)

Replace section 12(6)(a) with:

> (a) relates to a therapeutic product that has been imported into New Zealand by the Crown or a Crown organisation under the Therapeutic Products Act 2023; and

Replace section 76(a) with:

> (a) relates to a therapeutic product that has been imported into New Zealand by the Crown or a Crown organisation under the Therapeutic Products Act 2023; and

Coroners Act 2006 (2006 No 38)

In section 9, definition of **medical procedure**, replace paragraph (b) with:

> (b) includes the administration or use of a therapeutic product (as defined in section 16 of the Therapeutic Products Act 2023)

Corrections Act 2004 (2004 No 50)

In section 3(1), definition of **drug**, replace paragraph (b) with:

> (b) a prescription medicine or pharmacist medicine (as defined in section 14 of the Therapeutic Products Act 2023):

In section 3(1), replace the definition of **medicine** with:

> **medicine** has the same meaning as in section 22 of the Therapeutic Products Act 2023

Costs in Criminal Cases Act 1967 (1967 No 129)

In section 4(5), replace "or the Resource Management Act 1991" with "the Resource Management Act 1991, or the Therapeutic Products Act 2023".

In section 7(3), replace "or the Resource Management Act 1991" with "the Resource Management Act 1991, or the Therapeutic Products Act 2023".

In section 10(2), replace "or the Resource Management Act 1991" with "the Resource Management Act 1991, or the Therapeutic Products Act 2023".

COVID-19 Public Health Response Act 2020 (2020 No 12)

In section 5(1), replace the definition of **pack** with:

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

Crown Organisations (Criminal Liability) Act 2002 (2002 No 37)

After section 6(1)(e), insert:

(f) a Crown-enforceable offence as defined in section 304 of the Therapeutic Products Act 2023.

Replace section 7(a) with:

(a) compliance with the obligations imposed by any of the following:

(i) the Building Act 2004:

(ii) the Exclusive Economic Zone and Continental Shelf (Environmental Effects) Act 2012:

(iii) the Health and Safety at Work Act 2015:

(iv) the Resource Management Act 1991:

(v) Part 3 of the Children's Act 2014:

(vi) the Therapeutic Products Act 2023; and

After section 10(1)(b)(vii), insert:

(viii) section 209 or 243 of the Therapeutic Products Act 2023; or

Customs and Excise Act 2018 (2018 No 4)

Repeal section 242(1)(b)(v).

After section 242(1)(b)(vi), insert:

(vii) the Therapeutic Products Act 2023.

Fair Trading Act 1986 (1986 No 121)

Replace section 27(5) with:

(5) No Order in Council may be made under this section in relation to a therapeutic product (as defined in section 16 of the Therapeutic Products Act 2023), except in relation to its price.

Food Act 2014 (2014 No 32)

Replace section 9(1)(c)(iii) with:

(iii) a therapeutic product; or

(iiia) a controlled drug or psychoactive substance (unless an Order in Council made for the purposes of paragraph (b)(vii) declares it to be so); or

After section 9(1), insert:

(1A) An Order in Council cannot be made for the purposes of paragraph (b)(vii) in relation to a therapeutic product.

In section 9(4), repeal the definition of **medicine**.

In section 9(4), insert in its appropriate alphabetical order:

Food Act 2014 (2014 No 32)—*continued*

therapeutic product has the meaning given by section 16 of the Therapeutic Products Act 2023.

Replace section 368(3)(d) with:

(d) the Therapeutic Products Act 2023; or

Hazardous Substances and New Organisms Act 1996 (1996 No 30)

In section 2(1), definition of **innovative medicine application**, replace "section 23A of the Medicines Act 1981" with "section 151 of the Therapeutic Products Act 2023".

In section 2(1), repeal the definition of **qualifying medicine**.

In section 2(1), definition of **qualifying organism**, replace "qualifying medicine" with "qualifying therapeutic product".

In section 2(1), replace the definition of **responsible chief executive** with:

responsible chief executive means, as the case may be,—

(a) the chief executive of the Authority; or

(b) the Regulator under the Therapeutic Products Act 2023; or

(c) the chief executive of the department for the time being responsible for the administration of the Agricultural Compounds and Veterinary Medicines Act 1997

In section 2(1), insert in their appropriate alphabetical order:

qualifying therapeutic product means a therapeutic product that—

(a) is or contains a new organism; and

(b) meets the criteria set out in section 38I(3)

therapeutic product means a medicine, a medical device, or an API as defined in sections 22, 24, and 28 of the Therapeutic Products Act 2023

Replace section 19(2)(bb) with:

(bb) the power to determine whether a therapeutic product is a qualifying therapeutic product or a veterinary medicine is a qualifying veterinary medicine to the responsible chief executive:

In section 19(2)(bc), replace "qualifying medicines" with "qualifying therapeutic products".

In section 27(f), replace "medicine" with "therapeutic product" in each place.

In section 38I(3), replace "qualifying medicine" with "qualifying therapeutic product".

In section 38I(3), replace "that—" with "that,—".

In section 38I(3)(a), replace "the dose and routes of administration of the medicine" with "having regard to the dose and route of administration or method of use, the therapeutic product".

Hazardous Substances and New Organisms Act 1996 (1996 No 30)—*continued*

In section 38I(4), replace "qualifying medicine" with "qualifying therapeutic product".

In section 38I(4)(a), replace "medicine" with "therapeutic product" in each place.

Replace section 38I(5)(a) with:

> (a) for any person to carry on an activity that is regulated under the Therapeutic Products Act 2023 with a qualifying therapeutic product unless the person is allowed to do so under that Act; or

In section 38J, replace "section 38" with "section 38I".

In section 38J(b) and (c), replace "medicine is a qualifying medicine" with "therapeutic product is a qualifying therapeutic product".

In section 38K(1)(a), replace "qualifying medicine" with "qualifying therapeutic product".

In section 38K(1)(b), replace "the qualifying medicine or" with "or using the qualifying therapeutic product or administering the".

In section 38K(1)(c), replace "the qualifying medicine or" with "or use the qualifying therapeutic product or administer the".

In section 38K(1)(d), replace "whom the qualifying medicine may be administered" with "or on whom the qualifying therapeutic product may be administered or used".

In the cross-heading above section 49A, replace "*medicines*" with "*therapeutic products*".

In section 49A, definition of **interested government agency**, replace "medicine" with "therapeutic product".

In section 49A, repeal the definition of **medicine**.

In section 49A, definition of **responsible Minister**, replace paragraph (g) with:

> (g) the Therapeutic Products Act 2023

In section 49A, insert in its appropriate alphabetical order:

> **therapeutic product** means a medicine, a medical device, or an API as defined in sections 22, 24, and 28 of the Therapeutic Products Act 2023 that is or contains a hazardous substance or new organism.

In section 49C(b), replace "medicine" with "therapeutic product".

In the heading to section 49D, replace "**medicine**" with "**therapeutic product**".

In section 49D(2)(a) to (d) and (3)(b), replace "medicine" with "therapeutic product".

In section 49E(2), replace "medicine" with "therapeutic product" in each place.

In section 49F(3)(a), replace "medicine" with "therapeutic product".

In section 49G, replace "medicine" with "therapeutic product" in each place.

In section 49H(2)(b), replace "medicine" with "therapeutic product".

Hazardous Substances and New Organisms Act 1996 (1996 No 30)—*continued*

In section 49I(1), replace "medicine" with "therapeutic product" in each place.

In section 49L(2), replace "medicine" with "therapeutic product".

In section 55(3), replace "Sections 23A to 23C of the Medicines Act 1981 apply (with the necessary modifications) to the Authority (as if it were the Minister of Health)" with "Subpart 3 of Part 4 of the Therapeutic Products Act 2023 applies (with the necessary modifications) to the Authority (as if it were the Regulator under that Act)".

In section 55(3)(c), replace "Minister of Health" with "Regulator".

In section 55(3)(c), replace "section 23B of the Medicines Act 1981" with "that subpart 3".

Human Tissue Act 2008 (2008 No 28)

In section 6, repeal the definition of **medicine**.

In section 6, insert in their appropriate alphabetical order:

> **manufacture**, in relation to a therapeutic product, has the same meaning as in section 42 of the Therapeutic Products Act 2023
>
> **therapeutic product** has the same meaning as in section 16 of the Therapeutic Products Act 2023
>
> **therapeutic purpose** includes the manufacture of a therapeutic product

In section 6, definition of **use**,—

(a) in paragraph (b), delete ", medicines, or both":

(b) in paragraph (c), replace "paragraph (e)" with "paragraph (e) or (ea)":

(c) in paragraph (d), replace "paragraphs (e) and" with "paragraphs (e) to":

(d) in paragraph (e), replace ", a medicine, or both" with "that is not a therapeutic product":

(e) after paragraph (e), insert:

> (ea) does not include use of that tissue in so far as—
>
> (i) it is, or is part of, a therapeutic product the supply of which is lawful under the Therapeutic Products Act 2023; or
>
> (ii) it is used in the manufacture of a therapeutic product that is lawfully carried on under the Therapeutic Products Act 2023; and

In section 55(1), definition of **blood**,—

(a) in paragraph (a)(ii) and (iv), replace "preparation of a substance for therapeutic use" with "manufacture of a therapeutic product":

(b) in paragraph (b)(i), replace "diagnostic" with "therapeutic".

In section 55(1), definition of **controlled human substance**,—

Human Tissue Act 2008 (2008 No 28)—*continued*

(a) in paragraph (a)(i) and (iii), replace "preparation of a substance for therapeutic use" with "manufacture of a therapeutic product":

(b) in paragraph (b)(i), replace "diagnostic" with "therapeutic".

In section 56(3)(d), replace "a medicine (other than a medicine" with "therapeutic product (other than a product".

In section 61(3)(d), replace "medicine (other than a medicine" with "therapeutic product (other than a product".

At the end of section 61(3), insert:

> **Guidance note**
>
> If human tissue is, or is part of, a therapeutic product it may be subject to advertising restrictions under the Therapeutic Products Act 2023 in addition to any restrictions under this section.

Land Transport Act 1998 (1998 No 110)

In section 2(1), repeal the definition of **prescription medicine**.

In section 2(1), definition of **qualifying drug**, replace paragraph (b)(ii) with:

> (ii) a prescription medicine (as defined in section 14 of the Therapeutic Products Act 2023); but

Maritime Transport Act 1994 (1994 No 104)

In section 20(1), replace "Medicines Act 1981" with "Therapeutic Products Act 2023".

In section 50(1)(e), replace "Medicines Act 1981" with "Therapeutic Products Act 2023".

In section 52(1)(b)(i)(A) and (ii), replace "Medicines Act 1981" with "Therapeutic Products Act 2023".

Misuse of Drugs Act 1975 (1975 No 116)

In section 2(1), definition of **controlled drug analogue**, replace paragraph (b) with:

> (b) a pharmacy medicine, pharmacist medicine, or prescription medicine (as defined in section 14 of the Therapeutic Products Act 2023); or

In section 2(1), repeal the definitions of **designated prescriber** and **standing order**.

In section 2(1), insert in their appropriate alphabetical order:

> **designated prescriber**, in relation to a controlled drug, means a health practitioner prescriber (as defined in section 14 of the Therapeutic Products Act 2023) for that drug, other than a medical practitioner, dentist, nurse practitioner, optometrist, or midwife
>
> **prescription** means a complying prescription (as defined in section 54 of the Therapeutic Products Act 2023)

Misuse of Drugs Act 1975 (1975 No 116)—*continued*

> **standing order** means a complying standing order (as defined in section 55 of the Therapeutic Products Act 2023)

In section 13(4), replace the definition of **pharmacy employee** with:

> **pharmacy employee** means a pharmacy worker as defined in section 53 of the Therapeutic Products Act 2023.

Ombudsmen Act 1975 (1975 No 9)

In Schedule 1, Part 2, repeal the items relating to Medicines Classification Committee and Medicines Review Committee.

Pae Ora (Healthy Futures) Act 2022 (2022 No 30)

In section 4, replace the definition of **pharmaceutical** with:

> **pharmaceutical** means a medicine, a medical device, or an NHP (as defined in sections 22, 24, and 29 of the Therapeutic Products Act 2023) or related product or related thing

In section 74(1), replace the definition of **pharmaceuticals** with:

> **pharmaceutical** means a medicine, medical device, or NHP (as defined in sections 22, 24, and 29 of the Therapeutic Products Act 2023) or related product or related thing.

Psychoactive Substances Act 2013 (2013 No 53)

Replace section 9(3)(c), (d), and (e) with:

> (c) a therapeutic product (as defined in section 16 of the Therapeutic Products Act 2023):

After section 16(2)(a), insert:

> (aa) whether the applicant has been convicted of an offence or had a civil penalty order made against them under the Therapeutic Products Act 2023; and

Repeal section 16(3)(c).

Public Safety (Public Protection Orders) Act 2014 (2014 No 68)

In section 3, definition of **prohibited item**,—

(a) paragraph (b), replace "section 3 of the Medicines Act 1981" with "section 22 of the Therapeutic Products Act 2023":

(b) paragraph (c), replace "Medicines Act 1981" with "Therapeutic Products Act 2023".

In section 92A, definition of **drug or alcohol requirement**, paragraph (a), replace "Medicines Act 1981" with "Therapeutic Products Act 2023".

Search and Surveillance Act 2012 (2012 No 24)

In the Schedule, insert in its appropriate alphabetical order:

Therapeutic Products Act 2023	212	Inspector may enter a home, marae or related building, or treatment or consulting room to exercise powers of inspection	Subpart 3
	215	Imported consignments may be detained by Customs pending testing	Section 159
	243	Inspector may enter and search a place to investigate and enforce compliance with Act, including obtaining evidential material	All (except sections 118 and 119)
	244	Inspector may obtain search warrant for purposes of s 243	Subpart 3
	247	Regulator may destroy certain things seized by the Regulator, an inspector, or Customs	Section 160

Sentencing Act 2002 (2002 No 9)

In section 4(4), replace "or Part 3 of the Children's Act 2014" with "Part 3 of the Children's Act 2014, or the Therapeutic Products Act 2023".

Smokefree Environments and Regulated Products Act 1990 (1990 No 108)

In section 2(1), definition of **tobacco product**, replace "(being a medicine in respect of which there is in force a consent or provisional consent given under section 20 or section 23 of the Medicines Act 1981) that is sold or supplied wholly or principally for use as an aid in giving up smoking" with "that has a market authorisation under the Therapeutic Products Act 2023 and whose authorised indications under that Act include use as an aid in giving up smoking".

In section 2(4)(b) and (c), replace "Medicines Act 1981" with "Therapeutic Products Act 2023".

In section 54(3), replace "the Minister of Health has given consent or provisional consent to the distribution of the product under the Medicines Act 1981" with "it has a standard authorisation or provisional authorisation under the Therapeutic Products Act 2023".

Substance Addiction (Compulsory Assessment and Treatment) Act 2017 (2017 No 4)

In section 4, definition of **drug**, replace paragraph (b) with:

Substance Addiction (Compulsory Assessment and Treatment) Act 2017 (2017 No 4)—*continued*

(b) a prescription medicine or pharmacist medicine (as defined in section 14 of the Therapeutic Products Act 2023)

Summary Proceedings Act 1957 (1957 No 87)

In section 2(1), definition of **infringement notice**, after paragraph (ji), insert:

(jk) section 283 of the Therapeutic Products Act 2023; or

Trade Marks Act 2002 (2002 No 49)

Replace section 98(2) with:

(2) Subsection (1) applies only to the use of a trade mark in relation to a therapeutic product that has been imported into New Zealand by the Crown or a Crown organisation under the Therapeutic Products Act 2023.

Veterinarians Act 2005 (2005 No 126)

In section 50(1)(a)(i)(C), replace "Medicines Act 1981" with "Therapeutic Products Act 2023".

Repeal section 89A(a)(vii).

After section 89A(a)(viii), insert:

(ix) the Therapeutic Products Act 2023; or

Notes

1 General

This is a consolidation of the Therapeutic Products Act 2023 that incorporates the amendments made to the legislation so that it shows the law as at its stated date.

2 Legal status

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

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

3 Editorial and format changes

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

4 Amendments incorporated in this consolidation

Pae Ora (Disestablishment of Māori Health Authority) Amendment Act 2024 (2024 No 5): section 43

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