Therapeutic Products Bill

Government Bill

Explanatory note

General policy statement

Overview

The Therapeutic Products Bill is intended to replace the current Medicines Act 1981 and Dietary Supplements Regulations 1985 to provide for the comprehensive, risk-proportionate regulation of therapeutic products.

Therapeutic products are medicines, medical devices, natural health products, and active pharmaceutical ingredients. They include—

- medicines made from biological components, gene therapies, and advanced cell and tissue therapies; and
- medical devices that are software, production systems, whole organs, and tissue grafts; and;
- natural health products that are traditional and herbal medicines, and vitamin and mineral supplements.

Therapeutic products are used by all New Zealanders in their everyday lives and in all parts of the health system.

Background

Currently, the Medicines Act 1981 is the primary legislation for enabling access to safe medicines and medical devices. That Act does not provide coverage of many products used in modern health care delivery.

Natural health products are currently regulated by the Dietary Supplements Regulations 1985 under the Food Act 2014. This regulatory arrangement does not provide an appropriate level of assurance that products imported and supplied in New Zealand are safe or made to the appropriate quality standards. It also does not adequately regulate health benefit claims made about natural health products.

New Zealand's exporters also suffer from the lack of a modern and flexible regime.

Purpose

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

- acceptable safety, quality, and efficacy or performance of medicines, medical devices, and active pharmaceutical ingredients across their life-cycle; and
- acceptable safety and quality of natural health products across their life-cycle.

Therapeutic products carry both benefits and risks. A guiding principle for regulating therapeutic products is that the likely benefits should outweigh the likely risks and their regulation should be proportionate to those benefits and risks.

A therapeutic product is one that is intended to be used by humans for a therapeutic purpose. This includes—

- preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for a disease, ailment, defect, or injury:
- testing the susceptibility of humans to a disease or an ailment:
- investigating, replacing, modifying, or supporting part of a human's anatomy:
- disinfecting medical devices:
- maintaining health and providing for human nutritional supplementation.

While therapeutic products can provide enormous benefits, they are not risk-free. The ingredients used in a product may be inherently risky (for example, many chemotherapies), harmful in large amounts (for example, many pain relievers) or present unique risks to different groups (for example, pregnant people, infants, or those taking other medicines).

Risk can also arise because of a product's manufacture, such as contamination or counterfeiting. The effectiveness or safety of products can be affected by improper handling and transportation, inappropriate supply, or administration or use by unqualified people.

Other guiding principles important in helping achieve the Bill's aim are that regulation of therapeutic products should support timely access to products, open and well-functioning markets, and innovation. Regulation should also support choice of, and equity of access to, therapeutic products. There should be co-operation with overseas regulators and, if appropriate, alignment with international standards and practice.

The Bill's aim and guiding principles mean therapeutic products will be regulated across their lifecycle with obligations being imposed on people involved in a product's supply chain.

Omnibus Bill

The Bill is an omnibus Bill introduced in accordance with Standing Order 267(1)(a). That Standing Order provides that an omnibus Bill to amend more than 1 Act may be introduced if the amendments deal with an interrelated topic that can be regarded as

implementing a single broad policy. That policy is to give effect to the Bill's purpose and guiding principles so as to regulate therapeutic products across their lifecycle.

Market authorisations

The Bill provides that therapeutic products must receive a market authorisation before they can be imported into, exported from, or supplied in New Zealand. Significant penalties attach to the unlawful importation, supply, or export of therapeutic products.

Market authorisations for medicines and medical devices are issued following an evaluation by the Regulator of a product's safety, quality, and efficacy or performance. The Bill empowers the creation of risk-proportionate approval pathways and the setting of relevant product standards. The Bill also allows products without a market authorisation to be imported into and supplied in New Zealand in limited circumstances. Controls on this activity will be set out in secondary legislation.

Market authorisations are required for natural health products imported into, supplied in, or exported from New Zealand in the course of business. Reflecting their generally lower-risk, natural health products will be evaluated against different standards than those for medicines and medical devices.

The Bill allows the Regulator to issue an export authorisation for a product that does not meet one or more criteria for a product supplied in New Zealand. This is intended to support the export of safe, quality products from New Zealand to overseas markets that have different requirements for therapeutic products.

Controlled activities and other activities involving therapeutic products

The Bill provides for the regulation of a range of controlled activities. For medicines and medical devices, controls are imposed on, among other, manufacturing, wholesale and non-wholesale supply, exporting, and conducting a clinical trial with the product. Additional controls are placed on the use of medicines, including prescribing, compounding, dispensing, and administering. Manufacturing and exporting a natural health product in the course of business are controlled activities, as is carrying on a pharmacy business.

While advertising is not a controlled activity, the Bill allows the regulator to impose restrictions on advertising of therapeutic products. The Bill does allow direct to consumer advertising of therapeutic products.

Regulator and regulatory matters

The Bill establishes a Therapeutic Products Regulator. The Regulator will be a public servant appointed by the Director-General of Health on the basis of their relevant knowledge and expertise. The Regulator will exercise their powers under the Bill independently of the Director General of Health and the Minister of Health, but may be subject to general policy directions issued by the Minister.

The Bill provides a broad cost recovery power with regulations able to impose fees and levies to fund the costs of administering the Bill.

The Bill provides the Regulator with a range of compliance and enforcement powers backed up by a comprehensive offence and civil penalty regime. Depending on the nature and circumstances of the conduct, a contravention of the Bill may result in an infringement notice, a fine, or imprisonment. Courts will be able to make a civil penalty order against a person who contravenes the Bill in the course of business. Where appropriate, the Regulator will also be able to seek injunctions and enter into enforceable undertakings if contraventions of the Bill are occurring.

To address safety issues arising after a therapeutic product enters the supply chain, the Regulator will have the power to issue a range of orders, including recall orders, advertising remediation orders, directions orders, and product moratorium orders.

As Crown organisations are large users of therapeutic products and also manufacture or import therapeutic products, the Bill applies to the Crown and extends criminal liability to Crown organisations for some contraventions of the Bill.

Regulations will be able to prohibit all activity with a product if it directly or indirectly exposes any individual to a risk of death, serious injury, or serious illness, and the risk cannot be adequately managed by the exercise of the Regulator's powers under the Bill. A prohibited product cannot be used or supplied unless a permit issued by the Regulator expressly allows it.

Effects on other legislation and statutory regimes

The Bill will repeal most provisions of the Medicines Act 1981, except those relating to pharmacy ownership, and revokes the regulations made under that Act. The Bill does not disturb current regulatory arrangements relating to medicinal cannabis or drugs controlled under the Misuse of Drugs Act 1975, or psychoactive substances controlled under the Psychoactive Substances Act 2013.

The Dietary Supplements Regulations 1985 under the Food Act 2014 will also be revoked, as they currently regulate edible natural health products.

Transitional provisions in the Bill provide that products that are currently consented under the Medicines Act 1981 will automatically receive a market authorisation under the Bill. Products that do not require a consent under the Medicines Act 1981 (such as medical devices and natural health products) and that were lawfully being supplied in New Zealand before the Bill commences will have a transitional period of 2 to 5 years to seek a market authorisation.

Similar transitional arrangements are made for people who are lawfully engaged in activities that are regulated under the Bill. Existing licences will continue as licences under the Bill, and people engaged in activities that do not currently require licences (such as conducting clinical trials) will have a transitional period in which to apply for a licence or permit under the Bill.

Departmental disclosure statement

The Ministry of Health is required to prepare a disclosure statement to assist with the scrutiny of this Bill. The disclosure statement provides access to information about

the policy development of the Bill and identifies any significant or unusual legislative features of the Bill.

A copy of the statement can be found at http://legislation.govt.nz/disclosure.aspx?type=bill&subtype=government&year=2022&no=204

Regulatory impact statement

The Ministry of Health produced 7 regulatory impact statements in November 2015, March 2016, December 2018, May 2021, and November 2022 to help inform the main policy decisions taken by the Government relating to the contents of this Bill.

Copies of these regulatory impact statements can be found at—

- https://www.health.govt.nz/about-ministry/information-releases/regulatory-impact-statements
- https://treasury.govt.nz/publications/informationreleases/ris

Clause by clause analysis

Part 1
Preliminary provisions

Clause 1 is the Title clause.

Clause 2 is the commencement clause. The Bill will come into force on a date appointed by Order in Council. If the Bill has not come into force before 1 September 2026, it comes into force on that date.

A very large amount of secondary legislation will need to be made before the Bill comes into force. Much of this will be technical and detailed rules made by the Regulator. As an indication, under the equivalent Australian Commonwealth Act there are approximately 2,500 pages of secondary legislation plus regulations of 100 to 150 pages under each of the Australian State Acts.

The backstop commencement date of 1 September 2026 is to allow adequate time for this secondary legislation to be developed, including allowing time for the consultation required by *clause 380*.

Clause 3 sets out the purpose of the Bill.

Clause 4 sets out the principles guiding the exercise of powers under the Bill.

Clause 5 indicates that the transitional, savings, and related provisions are set out in *Schedule 1*.

Clause 6 provides that the Bill binds the Crown. Most importantly, it provides that a Crown organisation (which include Crown entities and departments) is treated as a separate person so they can be a sponsor, licensee, or permit holder in the same way as any other person. *Subpart 8 of Part 8* sets out more detail about how the Bill may be enforced against the Crown.

Clauses 7 to 13 provide an outline of the regulatory scheme established by the Bill.

Part 2
Interpretation

Subpart 1—General

Clause 14 defines terms used in the Bill. Most of the definitions are complex so are set out in separate clauses, either in *clauses 15 to 66* or in the part of the Bill where the term is relevant.

Subpart 2—Therapeutic products

Clauses 16 to 19 explain what therapeutic products are. A therapeutic product is any product that is intended for use in, on, or in relation to humans for a therapeutic purpose. Therapeutic purposes are listed in *clause 15*.

The meaning of intended for use is explained in *clause 17*.

Clause 19 allows the regulations to bring a product that would not otherwise be a therapeutic product into the scheme, or to remove what would otherwise be a therapeutic product from the scheme.

These regulations can only be made if the criteria in *clause 19* are met. Importantly, before removing a product from the scheme, the Minister has to be satisfied that the product is of sufficiently low risk that regulating it is not necessary or that if it is not regulated as a therapeutic product it would be adequately regulated by other means. For example, there are some products that meet the definition of therapeutic product but are very similar to products that are food. If the Minister is satisfied that such a product would be more appropriately regulated under the Food Act 2014, that might justify making regulations to declare it not to be a therapeutic product.

Active ingredients for medicines are therapeutic products even though they are not intended directly for use on humans.

Therapeutic products are divided into 4 types: medicines, medical devices, APIs (active pharmaceutical ingredients), and NHPs (natural health products) (*see clause 20*). The Bill regulates them differently because, by their nature, they have different benefits and risks.

Most therapeutic products will be clearly one type or another. However, there are some borderline cases (for example, a coronary stent with a heparin coating is a medicine and medical device hybrid). *Clause 21* allows the Regulator to make rules classifying these products so they are regulated most appropriately.

Clause 21(5) allows the Regulator to reclassify an NHP as a medicine at the request of the sponsor (which is something they may have commercial reasons for doing even though it will be subject to much more stringent regulation).

Medicines

A therapeutic product is a medicine if it achieves its principal intended action by pharmacological, immunological, metabolic, or genetic means, unless it is an API or NHP (*see clause 22*).

In addition to what are ordinarily thought of as medicines, this includes such things as living cell and tissue products (for example, patient-specific gene therapies).

Clause 23 provides for 4 primary classes of medicines: prescription medicines, pharmacist medicines, pharmacy medicines, and general sale medicines. All medicines will be in 1 of these classes. Different levels of restrictions apply to the different classes based on the likely benefits of, and risks associated with, medicines in each class. The regulations will set the criteria by which medicines are to be classified and the Regulator will make rules identifying the classes of medicines that are prescription, pharmacist, pharmacy, and general sale medicines. The market authorisation for a medicine will identify which class it is in.

The Bill also provides for 2 other groups of medicines—

- biologics (*see clause 32*); and
- medicines that require compounding, which are medicines that have to be specially made by a pharmacist for each patient (*see clause 37*).

Medicines in these groups will usually be prescription medicines, but that does not have to be the case. These 2 groups also overlap with each other because a biologic medicine might require compounding.

Regulations and rules will be made for the purposes of many provisions of the Bill. They may make different provision with respect to different classes of medicines (*see* section 49 of the Legislation Act 2019). Those classes may be subsets of the classes referred to in *clause 23* or classes whose criteria do not relate to the *clause 23* classes.

For example, rules under *clause 72(1)(f)* about transporting medicines might include requirements for medicines that have to be kept refrigerated regardless of whether they are prescription, pharmacist, pharmacy, or general sale medicines.

Medical devices

A therapeutic product is a medical device if it achieves its principal intended action by means other than pharmacological, immunological, metabolic, or genetic means (*see clause 24*). Any therapeutic product that is not a medicine, API, or NHP is a medical device. This includes a vast array of products from tongue depressors and bandages to implantable devices (such as pacemakers), diagnostic software, and robotic surgery machines.

Clause 25 relates to medical devices that are personalised for a particular patient. These are divided into 3 groups depending on the degree of personalisation and how they are produced.

Adaptable devices are devices that are manufactured as a standard device and then personalised for each patient (for example, a mass produced surgical implant that is adjusted to fit the patient when it is implanted).

Patient-matched and custom-made devices are devices that are personalised before they are manufactured. Whether a device is patient-matched or custom-made depends on how it is produced not what kind of device it is. Many devices (such as dental crowns, prosthetic limbs) that were previously custom-made are now made using standard production system with computer-aided design and manufacturing technology. Devices produced in that way are now patient-matched devices.

Some devices can now be produced by health practitioner at the point of care. For example, dentists are able to use ceramic milling systems in their consulting rooms to produce dental crowns for patients as they are being treated. This is an example of a device production system used to produce a patient-matched device.

Clause 26 relates to software as a medical device. Many medical devices include some software, but software as a medical device is a medical device that consists only of software.

Computer-aided detection software that performs image processing to help detect breast cancer is an example of software as a medical device under *clause 26(1)*.

Software for diagnosing a condition using the accelerometer that operates on the embedded processor on a consumer digital camera is likely to be software as a medical device under *clause 26(2)*.

The Bill does not establish classes of devices as it does for medicines. Instead *clause 27* allows the rules to establish categories of supply-restricted devices and use-restricted devices and impose restrictions on their supply or use.

Because of the range of different medical devices, the nature of the restrictions will vary considerably. There are many for which there will likely be no supply or use restrictions (such as bandages intended for household use). There are others for which there will be significant restrictions (such as implantable devices or robotic surgery machines).

APIs (active pharmaceutical ingredients)

A therapeutic product is an API if it is intended for use as an active ingredient of a medicine (*see clause 28*).

The Bill only regulates the manufacture and wholesale supply of APIs. Once an API is incorporated into a medicine, the Bill regulates the medicine.

NHPs (natural health products)

Under *clause 29*, a therapeutic product is an NHP if it consists only of 1 or more of the NHP ingredients listed in *clause 30* and permitted additives or formulation aids.

The rules will list a subset of NHP ingredients as recognised NHP ingredients. An NHP will only be able to obtain a market authorisation if its NHP ingredients are limited to those listed as recognised NHP ingredients.

Clause 29 also provides for a second category of NHPs. These are products that contain 1 or more ingredients that are not NHP ingredients, but which qualify as low concentration NHPs under *clause 31*.

Clause 30 defines NHP ingredient, recognised NHP ingredient, and additive or formulation aid.

Clause 31 defines low concentration NHPs. These are products in which the concentration of every ingredient in it (other than an additive or formulation aid) is not more than 20 parts per million. The concentration of ingredients in many homeopathic products is in this range. To qualify as a low concentration NHP a product must also meet the criteria in *clause 31(1)*.

Other terms relating to therapeutic products

Clause 32 provides for a medicine, a medical device, or an API to be a biologic if it contains human or non-human cells (including whole organs), viruses, and material derived from those cells or viruses.

Clause 33 allows the regulations to declare a therapeutic product to be a prohibited product. *Clause 74* then prohibits all activities with it. However, *clause 33* sets a very high threshold that must be met before something can be declared a prohibited product.

Clause 34 defines reportable products and critical needs products. These are products that are on Pharmac's pharmaceutical schedule (and are therefore Government funded) and other products where a shortage would have serious health consequences. There are obligations to report likely shortages of these products.

Subpart 3—Activities

The Bill regulates who can carry on various activities with therapeutic products. Those activities, and various related terms, are defined in *subpart 3 of Part 2*.

Clause 35 defines administering a medicine or an NHP as internal or external administration, including preparing it for administration.

Clause 36 defines a clinical trial. It covers trials of medicines or medical devices for the purpose of collecting information about their safety, efficacy, or performance. It only covers trials that involve administering the medicine to, or using the device on, participants. It does not cover studies that only involve collecting information.

Clause 37 defines compounding a medicine, which means producing a quantity of it ready for supply to a specific patient. This is an activity ordinarily carried on by a pharmacist when they fill a prescription for a medicine that does not have a market authorisation. This is most commonly done by hospital pharmacists.

Clause 38 defines dispensing a medicine, which means to bring a medicine to a state ready for immediate supply to a specific patient. This may include ascertaining the amount of the medicine required for the patient, packing it, and labelling it for the patient. This is also an activity ordinarily carried on by a pharmacist when they fill a prescription.

Clause 39 defines exporting as sending or taking a therapeutic product out of New Zealand. However, if a product is transhipped through New Zealand and remains under the control of Customs, when it leaves New Zealand, that is not considered to be exporting.

In relation to software as a medical device, *see* the next note about *clause 40*.

Clause 40 defines importing as bringing a therapeutic product into New Zealand. However, if a product is transhipped through New Zealand and remains under the control of Customs, that is not considered to be importing.

Software that is a medical device is not a physical thing so it can't be said to be in a particular place, and because it is usually made available over the internet, it can't be said to move from one place to another. The concept of importing software as a medical device does not have much meaning. Therefore, importing software as a medical device is defined to mean making it available for use by persons in New Zealand.

Clauses 41 to 48 define manufacturing.

Manufacturing a therapeutic product usually involves many steps that may be carried out by different people. Anyone who does any of those steps is a manufacturer of the product. Some requirements of the Bill apply to all manufacturers of a product, but most apply only to the responsible manufacturer.

Clause 42 defines the responsible manufacturer of a therapeutic product to be the person who is in fact primarily responsible for its manufacture. The clause lists various factors that are relevant in determining who the responsible manufacturer is.

In the case of a device produced using a device production system or a remanufactured device, *clause 45 or 46* may result in a different person being the responsible manufacturer.

Clause 43 defines manufacturing a medicine. It covers everything that is part of producing the medicine or bringing it to its final state. For a biologic medicine, it also includes procuring the biologic component (such as collecting blood from a donor) and processing and storing it.

Clause 44 defines manufacturing a medical device. It covers everything that is part of producing the device or bringing it to its final state.

For a biologic device, manufacturing also includes procuring the biologic component and processing and storing it.

For software as a medical device or a device that includes software, manufacturing includes developing the software.

If a device is remanufactured, manufacturing the device includes everything that is involved in remanufacturing it (*see clause 46*).

If a device is produced using a device production system, *clause 45* is also relevant.

If a person uses a device production system to produce a medical device for a patient and all the requirements in *clause 45(1)* are complied with, the manufacturer of the

system is deemed to be the responsible manufacturer of the device rather than the person who used the system to produce a device.

However, if someone uses a device production system to produce a medical device and any of the requirements in *clause 45(1)* are not complied with, the person who used the system is the responsible manufacturer of the device, and the manufacturer of the system has no responsibility for it.

Clause 46 defines remanufacturing a medical device. Remanufacturing involves changing a medical device in a way that would have a significant impact on its safety, quality, or performance. However, carrying out repairs, maintenance, upgrades, etc. do not constitute remanufacturing.

If someone remanufactures a device, it becomes a different device and the person who carried out the remanufacturing becomes the responsible manufacturer in place of the manufacturer of the original device.

Clause 47 defines manufacturing an API, which is very similar to manufacturing a medicine.

Clause 48 defines manufacturing an NHP. It covers everything that is part of producing the NHP or bringing it to its final state. It also covers the activities involved in producing the NHP ingredients (*see clause 30*).

Clause 49 defines off-label use. A medicine or medical device with a market authorisation is authorised for 1 or more purposes or indications (called authorised indications) set out in its market authorisation. If the medicine or device is used for a different purpose or indication, that is referred to as off-label use.

Clause 50 defines pharmacy business and pharmacy activity.

A business or undertaking is a pharmacy business if its activities include compounding or dispensing medicines, or supplying prescription or pharmacist medicines. If a business or undertaking is a pharmacy business, then their activities of supplying pharmacy medicines and any wholesale supply of medicine or medical device are also taken to be part of the pharmacy business.

Clause 51 defines pharmacy licence requirements, which are the minimum requirements that a pharmacist must meet when they carry on controlled activities.

Clause 52 defines pharmacy worker and what it means for a pharmacy worker to be qualified. Qualified pharmacy workers are allowed to carry on certain controlled activities (*see clause 82*).

Clause 53 explains what a prescription is and what the requirements are for it to be a complying prescription. A complying prescription is required to enable the non-wholesale supply of a prescription medicine (*see clause 70*).

Clause 54 explains what a standing order is, the requirements for it to be a complying standing order, and when it comes into, and ceases to be, in force.

An example of a standing order is the patient notes written by a doctor for a hospital patient to allow nurses to give a particular medicine to the patient.

Clause 55 defines supply to mean supply of a therapeutic product in New Zealand. It covers any kind of supply of a therapeutic product regardless of how it is supplied, how much is supplied, whether it is paid for, or whether the supplier and recipient are in the same place (so it includes online sales).

For the reasons explained in relation to importing, for software as a medical device, supply means to make it available to persons in New Zealand (*see notes for clause 40*).

Many provisions in the Bill refer to supplying a product to a patient. *Clause 55(4)* means that this covers supplying it to a person who has authority to receive it for the patient. For example, a pharmacist supplying a child's medicine to their parent, or a hospital pharmacist supplying a patient's medicine to a nurse so it can be given to the patient.

Supply is divided into wholesale supply and non-wholesale supply. *Clause 56* defines those terms.

Wholesale supply of a therapeutic product means supply to someone who is going to use it in the course of their business or undertaking (such as supply to a pharmacist, a doctor, or a hospital). Note that business or undertaking is defined in *clause 14*.

Non-wholesale supply means any supply of therapeutic product that is not wholesale supply.

All supply of an API is wholesale supply.

Clause 57 lists the activities that are supply chain activities. Anyone who carries on any of these activities is a person in the supply chain.

Clause 58 defines what it means to use a medical device. This is the device equivalent of administering a medicine.

Subpart 4—Other terms

Clause 59 provides for the Regulator to make rules setting standards for products that are exported. Export standards are minimum standards that a product must meet before an export authorisation can be issued. Once a product has an export authorisation, the sponsor must ensure that it continues to meet those standards. Export standards may also apply to products with a NZ authorisation if they are exported.

Clause 60 sets out the matters that the Regulator must have regard to when determining whether someone is a fit and proper person for the purposes of a particular provision of the Bill. None of these matters is determinative. For example, a person who previously held a licence under a relevant law that was suspended, is not automatically excluded from being a fit and proper person—that is just one of the matters that the Regulator will consider.

Clause 61 defines health benefit claim and permitted health benefit claim.

The sponsor of an NHP is allowed to make only permitted health benefit claims (*see clause 192*). Rules made for *clause 62* will set out standard health benefit claims that can be made about NHPs.

If an NHP has a market authorisation, its authorisation will identify which of the standard health benefit claims can be made about the NHP and may set out additional custom health benefit claim, if the Regulator is satisfied they are substantiated.

For an NHP that does not have a market authorisation, the only permitted health benefit claims are those in the rules that apply to the product.

Clause 62 provides for the rules setting out the standard health benefit claims. The Regulator may only include a health benefit claim in the rules if satisfied that the claim is substantiated. The claim may be substantiated by scientific evidence, evidence of traditional use, or both. Information about the traditional use of a product or ingredient that is in a pharmacopeia listed in the regulations is prima facie evidence of that use.

Clause 63 provides for the Regulator to make rules setting product standards. They may relate to any of the matters listed in this clause or any other matters the Regulator thinks are appropriate. Product standards are minimum standards that a product must meet before a market authorisation can be issued. Once a product has a market authorisation, the sponsor must ensure that it continues to meet those standards.

Clause 64 defines senior manger. This is relevant for *subpart 9 of Part 8* relating to the attribution of liability between a body corporate and its senior managers.

Clause 65 defines special case requirement. Various provisions of the Bill allow a health practitioner or veterinarian to carry on certain controlled activities with a medicine or medical device that does not have a NZ authorisation. Satisfying the special case requirement is one of the preconditions of them doing so.

Clause 66 defines what it means to work and to be a worker.

Part 3
Dealing with therapeutic products

Part 3 is the most important part of the Bill. It establishes the regulatory regime for therapeutic products in New Zealand. There are 2 components to the scheme—

- market authorisation requirements, which regulate which therapeutic products may be imported into, supplied in, or exported from New Zealand; and
- controlled activity and supply chain activity requirements, which regulate how those products may be dealt with and by whom.

Medicines, medical devices, and NHPs are all subject to market authorisation requirement. APIs are not because they will only reach the market once they have been incorporated into medicines. All therapeutic products (including APIs) are subject to controlled activity and supply chain activity requirements. Different requirements apply to different products and in different circumstances.

Subpart 1—Market authorisation requirements

Clause 67 prohibits a person from importing, supplying, or exporting a medicine or medical device, or from importing, supplying, or exporting an NHP in the course of a business or undertaking, unless the product has the requisite market authorisation.

Not complying with *clause 67 or 68* may be an offence, civil penalty contravention, or infringement offence (*see subparts 2 to 5 of Part 8*).

There are 3 kinds of market authorisations—

- standard—which is the usual authorisation allowing a medicine, a medical device, or an NHP to be imported, supplied, and exported:
- provisional—which authorises a medicine or medical device on a provisional basis 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):
- export—which authorises a medicine, a medical device, or an NHP for export even though it does not have an authorisation to be supplied in New Zealand.

A NZ authorisation refers to a standard or provisional authorisation.

Part 4 sets out the criteria and process for obtaining a market authorisation and other matters such as scope, duration, conditions, variations, and cancellation of market authorisations as well as the obligations of sponsors (that is, the holders of market authorisations).

If a product does not have the requisite market authorisation, *clause 67(2)* allows a person to import, supply, or export it if—

- a provision of *subpart 3 of Part 3,* a licence, or a permit allows them to do so; or
- it is a low concentration NHP.

Clause 68 prohibits a person from importing a medicine, a medical device, or an NHP with a market authorisation in the course of a business or undertaking unless they are the product's sponsor, they have the sponsor's consent, or they are allowed to import it without the sponsor's consent.

Subpart 2—Controlled activities and supply chain activities

Clause 69 prohibits a person from carrying on a controlled activity unless they are allowed to do so by a provision of *subpart 3*, a licence, or a permit.

Not complying with *clause 69* or any of the other provisions in this subpart may be an offence, civil penalty contravention, or infringement offence (*see subparts 2 to 5 of Part 8*).

The controlled activities are listed in *clause 69(2)*.

A person who is allowed to carry on a controlled activity is subject to the limitations in the relevant provision of *subpart 3* or their licence or permit, as well as requirements in the rules under *clause 72* (*see* notes below).

Clause 70 prohibits a person from supplying a prescription medicine by non-wholesale supply unless the person is a recognised prescriber (that is, a health practitioner or veterinarian who would be allowed to issue a prescription for the medicine) or a licence, permit, or provision of *subpart 3* allows the person to supply it.

Clause 71 prohibits a person from administering an NHP by injection or parenteral infusion.

Clause 72 requires a person in the supply chain to comply with any requirements in the rules about any of the matters listed in that clause.

The rules can make provide different requirements on any differential basis, for example, for different people, different products, and different circumstances (*see* sections 49 and 50 of the Legislation Act 2019).

Before making the rules, the Regulator must be satisfied that the requirements are appropriate and proportionate having regard to the likely benefits of, and risks associated with, the therapeutic products they apply to (*see clause 377*) and consult people likely to be affected (*see clause 380*).

Clause 73 requires a person in the supply chain to ensure that they and anyone working for them meet any qualification, training, and competency requirements set by the regulations.

Clause 74 prohibits anyone from carrying on any of the listed activities with a prohibited product. This applies to everyone, whether or not they are carrying on a business or undertaking. This reflects the severity of the risks associated with the product (*see clause 33*). If a product becomes prohibited the Regulator could issue a prohibited product under *clause 226* to remove any of the product that is currently in the supply chain.

Clause 75 prohibits the supply of medicines from a vending machine unless the relevant provision, licence, or permit expressly allows it.

Subpart 3—When activities are allowed

Subpart 3 of Part 3 of the Bill allows certain classes of people to import, supply, or export a product that does not have a market authorisation or to carry on a controlled activity without needing a licence or permit if they meet specified requirements.

Each provision of *subpart 3* applies for the purposes of specific provisions in *subparts 1 and 2 of Part 3*, so allows something to be done that would otherwise be unlawful under that provision.

For example, *clause 77* applies for the purposes of *clause 69(1) and (2)(a)(vi)* (which prohibit a person dispensing a medicine). *Clause 77* sets out the circumstances in which a pharmacist is allowed to dispense medicines.

Note that *subpart 3* sets out the circumstances in which a person is allowed to do something that would otherwise be unlawful under *subparts 1 and 2*. It is therefore not a comprehensive list of what a person may do. For example, there is no provision allowing a pharmacist to supply general sale medicines—because supplying those

medicines is not a controlled activity a pharmacist does not need a provision in *subpart 3* to allow them to do so.

If *subpart 3* allows a person to do something, they must still comply with the rest of the Bill, including the rules under *clause 72*.

Pharmacists and pharmacy workers

Clauses 76 to 81 allow a pharmacist to supply, export, and import medicines and medical devices and to compound and dispense medicines in the circumstances set out in those clauses.

Clause 82 allows persons working in a pharmacy to carry on activities that the pharmacist is allowed to do provided they are qualified to do so and are supervised by the pharmacist.

Health practitioners and health practitioner's workers

Clauses 83 to 91 allow health practitioners to—

- prescribe, administer, dispense, supply, export, and import medicines:
- supply, export, and import medical devices and produce devices using a device production system:
- issue standing orders.

Not all health practitioners are allowed to carry on all of these activities. *Clauses 83 to 91* allow a health practitioner to carry on an activity only if doing so is within their scope of practice under the Health Practitioners Competence Assurance Act 2003. Therefore, which practitioners are allowed to carry on which activities and with which products is determined under that Act, not this Bill.

Clause 92 allows a person who works for a health practitioner to supply a pharmacy medicine under the supervision of the health practitioner.

What it means to work for a business or undertaking or for a person is explained in *clause 66*.

Veterinarians

Clauses 93 to 100 allow a veterinarian to supply, prescribe, administer, dispense, and export medicines, to supply and export medical devices, and to produce devices using a device production system.

Although this Bill relates to therapeutic products for humans, many therapeutic product are also used for treating animals, particularly dogs and cats and other small animals. These clauses allow veterinarians to use human therapeutic products. Whether they do so is a clinical decision for the veterinarian.

Veterinarians' workers

Clause 101 allows a person who works for a veterinarian to carry on controlled activities under the supervision of the veterinarian.

Person acting under standing order

Clause 102 allows a person who is authorised by a complying standing order to do so to supply or administer medicines in accordance with the order.

Clause 54 sets out the requirements for a complying standing order and what it can authorise a person to do.

Downstream activities

If a health practitioner supplies a prescription medicine, pharmacist medicine, or pharmacy medicine directly to a patient, no-one else would be involved in the medicine reaching the patient. However, it is very often the case that there are other people involved before the medicine reaches the patient. A pharmacist will often need to dispense the medicine, it may pass through several pairs of hands before reaching the patient, and someone may need to administer it to the patient.

Some of these downstream activities are covered by other provisions in *subpart 3* (such as *clauses 77 and 78* allowing the pharmacist to dispense and supply the medicine).

Clause 55(4) means that if a person is allowed to supply a medicine to a specific patient they are allowed to supply it to someone else on behalf of the patient. For example, if a pharmacist supplies a prescription medicine to a family member of the patient, that would satisfy the requirement in *clause 70(a)* that it must be supplied to the patient.

Particularly in a hospital or health case setting, there may be a number of people who pass the medicine to each other before it reaches the patient. *Clause 103* allows each of those persons to supply it to the next and, if necessary, for it to be administered to the patient.

Possession of prescription medicines or prescription APIs

Clause 104 allows anyone to whom a prescription medicine has been lawfully supplied to have possession of it. This covers all of the people in the chain of supply between the health practitioner and the patient.

Clause 104 also allows anyone who is allowed to carry on a controlled activity with a prescription medicine (such as a pharmacist or person conducting a clinical trial) to have possession of it for that purpose. It makes similar provision for people in possession of prescription APIs.

Personal use imports

Clauses 105 and 106 allow for personal use importation of medicines and medical devices that do not have a NZ authorisation. There are detailed restrictions limiting how much can be imported and on what conditions. Arranging for a medicine to be sent from overseas (such a buying it online from an overseas website) is importing. If an online purchase meets all the criteria in *clause 105(4)*, the person is allowed to import the medicine. If the criteria are not met, *clause 105* would not apply, and importing the medicine would contravene *clause 67*.

Clause 106 sets out equivalent requirements for medical devices although the conditions are less stringent.

In relation to NHPs, *clause 67* prohibits importing in the course of a business or undertaking. It does not prohibit importing for personal use. Therefore an equivalent of *clause 105* is not needed for NHPs.

Personal exports

Clause 107 allows an individual to export a medicine or medical device, whether or not it has a market authorisation, if the person acquired the product lawfully, is not acting in the course of a business or undertaking, and in the case of a medicine, the amount being exported is not more than 3 months' supply.

Manufacture of custom-made devices

Custom-made devices cannot be evaluated in the way other devices are because every device is manufactured from scratch for a specific patient. A person who manufacturers these devices therefore needs to be allowed to do so even though the device does not have a market authorisation. *Clause 108* provides for the regulations to identify classes of persons who can manufacture custom-made devices. A person in such a class can then manufacture a device for specific patients at the request of a health practitioner or veterinarian as long as they comply with any requirements in the rules.

Clause 109 provides for the regulations to identify classes of persons who are allowed to use a device production system to produce a patient-matched devices. A person in such a class can then produce a device for specific patients at the request of a health practitioner or veterinarian as long as they comply with any requirements in the rules.

Sponsors of medicines or medical devices

Clause 110 allows the sponsor of a medicine or medical device to export it without needing a licence.

NHPs

Clause 111 allows the sponsor of an NHP with a market authorisation to manufacture or export it without needing a licence.

Clause 112 allows an NHP practitioner to manufacture and supply an NHP that does not have a market authorisation if it is manufactured for a specific client after the practitioner has determined that it is appropriate for the client and the other criteria in the clause are met. If the client is overseas but is ordinarily resident in New Zealand, the NHP practitioner can export it to the client.

Cessation of market authorisation

Clause 113 deals with the situation where a product's market authorisation ceases (for example, because it is cancelled or the sponsor goes into liquidation) and provides a mechanism for dealing with stock that is already in the supply chain. If the Regulator makes a use of current stock notice, people in the supply chain are allowed to continue using that stock even though it no longer has an authorisation.

The Regulator does not have to issue a use of current stock notice. If they thought it was not appropriate (because, for example, there was a risk that current stock was contaminated), the Regulator may take other action, such as issuing a recall order under *clause 214*.

Clause 114 also provides for a current stock notice to be used if a major change is made to a product but a market authorisation has not been issued for the changed product.

The Regulator does not have to issue a use of current stock notice. If they thought the product had been changed in a way that poses a significant risk to personal health or public health, the Regulator may take other action, such as issuing a product moratorium order under *clause 222*.

Other classes of persons specified in regulations

Clause 115 allows regulations to be made allowing other classes of persons to carry on controlled activities or do something that would otherwise contravene *clauses 67 to 71*. A person in such a class may carry on the activity if they comply with any requirements in the rules.

This power could be used to address unexpected situations when it is necessary to authorise a class of person to do something they would not normally be doing. For example, to facilitate the rollout of the COVID-19 vaccine, arrangements had to be made to allow pharmacists and vaccinators to administer the vaccines. Under the Bill that could easily be done by making regulations identifying who can be a vaccinator and allowing them to administer vaccines. The Regulator would simultaneously make rules setting out the more detailed requirements such as where and when they can work, who they can vaccinate, the dose they can use, the records that need to be kept, what kind of supervision is needed, etc.

Regulations made for this clause are not limited to urgent or short term situations. For example, if new technology is developed, it may become appropriate to allow a new class of persons to use it to carry on a controlled activity.

Emergency arrangements

Clause 116 provides for emergency situations. It allows the chief executive of the Ministry to make an emergency arrangements notice allowing a person or class of persons to do something that would otherwise contravene a provision of *subpart 1 or 2*.

A situation justifying the exercise of such a power (such as a natural disaster or pandemic) is very likely to be one that requires a whole-of-Government response rather than being something related only to therapeutic products. It is therefore more appropriate for this power be exercisable by the chief executive than the Regulator, although the Regulator must be consulted before a notice is made.

Part 4
Market authorisations for medicines, medical devices, and NHPs

Subpart 1—Market authorisations

As explained above, *clause 67* requires a medicine, a medical device, or an NHP to have a market authorisation before it can be imported, supplied, or exported.

Kinds of market authorisations

Clause 117 explains the 3 types of market authorisations: standard, provisional, and export.

A standard authorisation is the usual authorisation that a medicine, a medical device, or an NHP would need for it to be made available in New Zealand. A standard authorisation also allows the product to be exported.

A provisional authorisation may be issued for a medicine or medical device if the Regulator is not able to determine whether it meets all the requirements for a standard authorisation. The Regulator would still have to be satisfied that the product's safety, quality, and efficacy or performance are sufficiently well established to justify allowing it to be made available in New Zealand. A provisional authorisation has a maximum duration of 2 years and will usually be subject to more stringent conditions than would apply to a standard authorisation.

A provisional authorisation might be issued, for example, where a market authorisation is being sought for a new medicine and the Regulator is satisfied of its safety and quality but there is not yet sufficient data to enable a full evaluation of its efficacy or performance. This was the case for the COVID-19 vaccines when they first received provisional consent under the Medicines Act 1981.

Where the Bill refers to a product with a NZ authorisation, it means a product that has either a standard authorisation or a provisional authorisation.

An export authorisation may be issued for a medicine, a medical device, or an NHP allowing it to be exported even though it does not have a NZ authorisation. The Regulator must still be satisfied of its safety, quality, and efficacy or performance (or for NHPs, its safety and quality) before issuing an export authorisation. An example of when an export authorisation might be issued is where a product meets all of the applicable product standards except those relating to labelling because the country to which it is to be exported has different labelling requirements.

Issuing of market authorisation for medicines and medical devices

Clause 118 provides for a person to apply for a market authorisation for a medicine or medical device.

The Regulator may issue a market authorisation for a product if they have evaluated it under *clause 119*, and are satisfied that the criteria in *clauses 120 and 121* are met and that it is appropriate to issue a market authorisation for the product.

Clause 119 sets out the requirements for evaluating a medicine or medical device. The purpose of the evaluation is for the Regulator to determine—

- whether the safety, quality, and efficacy or performance of the product for its intended indications are satisfactorily established; and
- whether the likely benefits of the product outweigh the likely risks associated with it.

Evaluating a medicine or medical device involves consideration of the product itself as well as the controls and restrictions that will apply to it if a market authorisation is issued. *Clause 119(3)* sets out some of the matters that may be considered.

For example, if the Regulator is evaluating a medical device and it meets all the criteria except one provision of the product standards, the Regulator may have regard to the fact that a market authorisation could disapply that provision of the product standard and if necessary impose an alternative requirement as a condition on the market authorisation.

Clause 120 sets out the criteria for a market authorisation for a medicine or medical device.

Clause 121 sets out the criteria for being a sponsor of a medicine or medical device. In determining whether someone is a fit and proper person to be a sponsor, the Regulator must have regard to the matters set out in *clause 60*.

Issuing market authorisation for NHPs

Clauses 122 to 125 provide for the issue of market authorisations for NHPs. They differ from the provisions relating to medicines to reflect the fact that the risks associated with NHPs are generally less than the risks associated with medicines.

Clause 122 provides for a person to apply for a standard authorisation or export authorisation for an NHP. A provisional authorisation is not available for NHPs.

The rules about how applications are to be made must provide for the applicant to assess whether the NHP meets the requirements for an authorisation and to make a declaration in their application that those criteria are met.

The Bill allows the Regulator to use automated systems to carry out their functions (*see clause 352*). It is intended that this power will be used to provide for applications for market authorisations for NHPs to be lodged through an online portal with applicants making a declaration that the criteria for an authorisation are met.

Making a false declaration is an offence under *clause 199* (giving misleading information to the Regulator) and would be grounds for the Regulator to cancel the market authorisation.

Clause 123 allows the Regulator to issue a market authorisation for an NHP if the criteria in *clauses 124 and 125* are met. For this purpose, the applicant's declaration that the criteria for an authorisation are met is prima facie evidence of that fact. However, the Regulator's can request further information under *clause 365* or reject the application under *clause 369* if there are grounds for doing so.

Clause 124 sets out the criteria for issuing a market authorisation for an NHP. They are similar to the criteria for medicines except that there is no requirement to establish the efficacy of the product. There is, however, a requirement that any proposed health benefit claims are substantiated.

Clause 125 sets out the criteria for being the sponsor of an NHP, which are the same as for sponsors of medicines and devices.

Content and scope of market authorisation

Clause 126 lists the details that must be included in a product's market authorisation.

Clause 127 allows a market authorisation to disapply a condition in the rules, product standard, or export standard that would otherwise apply to the product.

Clause 128 sets out the scope of a product's market authorisation. The authorisation applies to the product as described in the market authorisation when the authorisation is issued and any subsequent minor changes. A minor change is any change that is not a major change, which is explained in *clause 129*.

A market authorisation for a medicine or medical device authorises the product only for the authorised indications set out in the authorisation. *See* the notes above in relation to the definition of off-label use in *clause 49*.

Under *clause 129*, if a therapeutic product is subject to a major change, the changed product is a different product from the original one. It is therefore not covered by the original product's market authorisation and a separate market authorisation would have to be obtained for it.

A major change is a change to the product itself or to any matter or information relating to it that may have a significant impact on the product's safety, quality, or efficacy or performance and is of a kind identified by the rules as a major change. A major change may occur even if the product itself is not changed. For example, if the same product is manufactured in a different place, that may have a significant impact on its quality.

Clause 130 prohibits a market authorisation being transferred to a different person unless the Regulator approves the other person as the product's new sponsor.

Duration of market authorisation

Clause 131 provides for the commencement and duration of market authorisations. Standard and export authorisations usually remain in force until they are cancelled. A provisional authorisation cannot be for more than 2 years.

A product can have successive provisional authorisations, but each time the sponsor would need to apply for an authorisation and satisfy the Regulator that the product still meets the criteria for a provisional authorisation.

Clause 132 provides that a market authorisation lapses if any of the events listed in that clause occur. If that does happen, *clause 113* may allow for continued use of stock that is already in the supply chain.

Conditions on market authorisation

Clause 133 makes a market authorisation subject to any conditions set out in the rules or imposed by the Regulator. The Regulator may impose conditions when the authorisation is issued or by varying the authorisation under *clause 134*.

Variation of market authorisation

Clause 134 allows for the variation of a market authorisation on application by the sponsor. A market authorisation cannot be varied so that it covers a different product. Therefore it cannot be varied to cover a product after a major change has been made it.

Clause 135 allows for the variation of a market authorisation by the Regulator on their own motion but only for limited purposes. Before doing so the Regulator must give the sponsor an opportunity to comment. This requires the Regulator to notify the sponsor of the Regulator's intention to make the variation and the reasons for doing so, allow the sponsor a reasonable time to make submissions, and take any submissions into account (*see clause 354*).

Cancellation of market authorisation

Clause 136 sets out the grounds on which a market authorisation may be cancelled. *Clause 137* allows the Regulator to cancel a market authorisation if those grounds exist. If grounds to cancel exist, the Regulator may vary the market authorisation under *clause 135* rather than cancelling it.

Clause 138 allows the Regulator to cancel a market authorisation on application by the sponsor.

Subpart 2—Obligations of sponsors

Subpart 2 of Part 4 imposes obligations on sponsors of therapeutic products. Not complying with any of these provision may be an offence, civil penalty contravention, or infringement offence (*see subparts 2 to 5 of Part 8*).

Clause 139 requires the sponsor of a therapeutic product to comply with the product's market authorisation and to ensure that the product conforms to the authorisation.

Clause 140 requires the sponsor of a therapeutic product to ensure that the product meets with the applicable product standards.

Clause 141 requires the sponsor of a therapeutic product with an export authorisation to ensure that the product meets the applicable export standards. It also requires the sponsor of a product with a NZ authorisation to ensure that any of the product that is exported meets any applicable export standards.

Clause 142 requires the sponsor of a therapeutic product to have a post-market surveillance and response system to provide surveillance of the product's safety and quality, and efficacy (for a medicine) or performance (for a medical device) and for the sponsor to respond to issues relating to those matters.

The system must provide for surveillance and responses that are appropriate and proportionate having regard to the likely benefits of, and risks associated with, the product. It must also comply with any requirements in the rules.

Clause 143 requires the sponsor of a therapeutic product to comply with any requirements in the rules about any of the matters listed in that clause. The rules will provide different requirements for different products so as to be appropriate and proportionate having regard to the likely benefits of, and risks associated with, different products.

Clause 144 requires the sponsor of a therapeutic product to notify the Regulator of any minor changes in relation to the product that are of a kind specified in the rules.

This notification is required because the product's market authorisation covers minor changes (*see clause 128*) so the Regulator needs to know what minor changes have been made. A notification of a minor change will be included on the register of therapeutic products so the public record of what is covered by the market authorisation is up to date.

Clause 145 requires the sponsor of a reportable product to notify the Regulator if there is likely to be a shortage of the product in the next 6 months. This is to give the Regulator time to put in place measures to deal with any negative consequences such a shortage might cause.

Clause 146 requires the sponsor of a reportable product to notify the Regulator if they intend to stop supplying the product. This is also to give the Regulator time to put in place measures to deal with any negative consequences that might flow from the product no longer being available.

Clause 147 provides that the obligations of the sponsor of a therapeutic product under *subpart 2* do not apply to products that were imported without the sponsor's consent.

Subpart 3—Protection of active ingredient information about innovative medicines

Subpart 3 of Part 4 provides for the protection of certain commercially confidential information relating to innovative medicines to ensure that the information, given to the Regulator for the purpose of obtaining a market authorisation for the medicine, cannot be disclosed or used for other purposes. These provisions give effect to New Zealand's obligations under international agreements.

Part 5
Licences and permits

Clause 69 of the Bill prohibits a person from carrying on a controlled activity unless a licence, permit, or provision of *subpart 3 of Part 3* allows them to do so. *Part 5* of the Bill provides for licences and permits.

Subpart 1—Licences

Clause 151 provides that a licence may be granted to allow a person to carry on 1 or more controlled activities. Licences are intended to allow people to carry on a business or undertaking doing at least 1 controlled activity on an ongoing basis. If a person wants to carry on a controlled activity for a short period or to do something on an ad hoc basis, a permit under *subpart 2* may be more appropriate.

In addition to allowing the licensee to carry on the controlled activity, it may also allow the licensee to do other things (for example, a licence allowing the licensee to supply medical devices might allow them to transport and store the devices is a way that is different from what is required by the rules under *clause 72*).

A licence may also allow other persons to do things (for example, a licence allowing the licensee to conduct a clinical trial of a medicine might allow someone else to import the medicine even though the medicine does not have a market authorisation).

Clause 152 lists the information that must be set out in a licence.

Clause 153 explains the effect of a licence for the licensee, for the licensee's workers, and for other persons who are specified in the licence as being allowed to do things.

A licence only allows things to be done in relation to a therapeutic product covered by the licence and only if they are done in accordance with the terms and conditions of the licence.

Clause 69 prohibits a person from carrying on a controlled activity unless a licence allows them to do so. It is not enough that the person holds a licence—to avoid breaching *clause 69*, they must be complying with the licence.

Clause 154 relates to pharmacy licences. A pharmacy licence allows the licensee to carry on the pharmacy business (*see clause 50*). It also means that pharmacists who are allowed to carry on those activities can do so at the licensed premises (*see* notes above about *clause 76*). However, a pharmacy licence does not allow anyone to compound, dispense, or supply a medicine unless they personally are allowed to do so (usually under a provision of *subpart 3 of Part 3*).

Clause 155 provides for the situation where a licence allows someone to import or supply a product that does not have a market authorisation and it is intended that the product will be available for use in New Zealand (for example, the licence for an importer who usually imports medicines that have market authorisations might also allow them, in emergency circumstances, to import certain medicines that do not have market authorisations). This clause allows the product to be treated as if it did have a NZ authorisation.

Clause 156 provides for the Regulator to grant a licence if the proposed licensee meets the criteria in *clause 157* and the criteria for granting a licence in *clause 158* are met. These include the requirement for licensees to have responsible persons who meet the criteria in *clause 159*.

In determining whether someone is a fit and proper person to be a licensee or responsible person, the Regulator must have regard to the matters set out in *clause 60*.

The role of responsible persons is explained in the notes below about *subpart 4 of Part 5*.

Subpart 2—Permits

Clauses 160 to 165 are the equivalent provisions for permits.

Permits are intended to be used for short-term or one-off situations, rather than for ongoing business activity. A permit may also be used to allow someone to do something more specific—for example, to permit someone in the supply chain to not comply with a particular requirement of the rules under *clause 72*.

The range of matters that may be permitted by a permit is very wide. The vast array of products that the Bill applies to and the range of people in the supply chain whose activities are regulated by the Bill means there is an enormous number of scenarios that might occur in which some of the requirements of the Bill are not appropriate or might be impossible to comply with. The wide power to grant permits will allow the Regulator to deal with those situations as they arise.

Note that the exemption power in *clause 379* does not allow an exemption to be granted to a specific person. A person wishing to be excused from compliance with a requirement of the Bill would need to obtain a permit.

Subpart 3—Provisions applying to licences and permits

Duration of licence or permit

Clause 166 provides the maximum duration for licenses and permits to be 5 and 2 years respectively.

Conditions on licence or permit

Clause 167 provides that a licence or permit is subject to any conditions set out in the rules or imposed by the Regulator.

Variation of licence or permit

Clause 168 provides for the variation of a licence or permit. The Regulator has power to make a variation on their own initiative, but must give the licensee or permit holder an opportunity to comment before doing so.

Suspension and cancellation of licence or permit

Clauses 169 and 170 set out the grounds on which a licence or permit may be suspended or cancelled. *Clause 171* allows the Regulator to cancel or suspend a licence or permit if those grounds exist. The Regulator is not required to cancel or suspend; they have a discretion to do so.

Clause 172 to 176 provide procedural requirements relating to, and for the effect of, a cancellation or suspension.

Transfer of licence or permit

Clauses 177 and 178 provide that a licence or permit is not transferable except in the limited circumstances set out in *clause 178*. Licences and permits are transferred in those circumstances to allow business and supply chain continuity in the short term while longer term arrangements are made.

Subpart 4—Obligations of licensees, permit holders, and responsible persons

Subpart 4 of Part 5 imposes obligations on licensees, permit holders, and their senior managers. It also imposes obligations on responsible persons (who are individuals who have oversight of the day-to-day operation of the activities of licensees) for the purpose of ensuring that the licensees comply with their licences and their obligations under the Bill.

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

Clause 179 requires a licensee to ensure that a responsible person has sufficient authority and resources to enable them to comply with their obligations.

Clause 180 requires a licensee or permit holder whose workers include health practitioners or veterinarians to ensure that those workers are able to act professionally and are not induced to do otherwise.

If a health practitioner or veterinarian were to act unprofessionally, they would be dealt with by the relevant responsible authority under the Health Practitioners Competence Assurance Act 2003 or the Veterinary Council of New Zealand under the Veterinarians Act 2005.

Clause 181 prohibits a licensee, permit holder, or a senior manager (which is defined in *clause 64*) of a licensee or permit holder from attempting to induce a health practitioner or veterinarian to act unprofessionally.

Clause 182 requires a licensee or permit holder to ensure that they and anyone working for them meet any qualification, training, and competency requirements set by the regulations.

Clause 183 requires a responsible person for a licensee to report to the licensee if they have reason to believe that the licensee or any of its senior managers or workers have, have attempted to, or intend to contravene the Bill or to induce someone to do so. If the licensee does not resolve the matter within a reasonable period, the responsible person must report it to the Regulator.

Clause 184 prohibits a licensee, or a senior manager of a licensee, from engaging in adverse conduct in relation to a responsible person for a retaliatory reason. This covers such things as terminating the person's employment or treating them less favourably than other workers in retaliation for the responsible person reporting matters to the Regulator. This is similar to the provisions of the protections provided by the Protected Disclosures (Protection of Whistleblowers) Act 2022 for a person who makes a disclosure under that Act.

Clause 185 requires a responsible person to comply with any requirements in the rules about any of the matters listed in that clause.

Clause 186 requires the licensee of a pharmacy licence to ensure that pharmacy activities (that is, compounding and dispensing medicines and supplying prescription or pharmacist medicines) are carried on only by persons who are allowed to do so.

Part 6
Other prohibited conduct

Part 6 prohibits various conduct relating to therapeutic products or the administration of the Bill. Not complying with a provision of this Part may be an offence, civil penalty contravention, or infringement offence (*see subparts 2 to 5 of Part 8*).

Tampering

Clause 187 prohibits a person from tampering with a therapeutic product, threatening to do so, or claiming to have done so.

Clause 188 prohibits a person in the supply chain from carrying on a supply chain activity with a therapeutic product that has been tampered with.

Clause 189 requires a sponsor or person in the supply chain to notify the Regulator of suspected tampering.

Misrepresentation

Clause 190 prohibits a person from making a misrepresentation about a therapeutic product. This includes representing that something is a therapeutic product when it is not. In that case, *Parts 7 and 8* of the Bill (which relate to the Regulator's regulatory and enforcement powers) apply to the thing as if it were a therapeutic product. This would, for example, allow the Regulator to make a recall order or directions order and to exercise their enforcement powers in relation to the thing.

Clause 191 prohibits a person from misrepresenting themselves or someone else to be a sponsor, licensee, permit holder, or someone who is otherwise allowed under the Bill to do something under the Bill, or to be lawfully able to carry on a supply chain activity.

Health benefit claims

Clause 192 prohibits the sponsor of an NHP from making health benefit claim about the NHP that are not permitted claims. The clause also applies to the manufacturer, importer, or exporter of an NHP that does not have a market authorisation.

Advertising

Clause 193 explains what an advertisement for a therapeutic product is and what it means to distribute it. The definitions are wide in order to ensure that all forms of advertising are covered.

Clause 194 prohibits a person from advertising a therapeutic product unless it has the appropriate market authorisation and complies with the advertising and distribution requirements.

In addition, if someone contravenes *clause 194*, the Regulator may make an advertising remediation order under *clause 218* to prevent continued or further distribution of the advertisement or reduce the risk posed by it.

Improper inducements to health practitioners or veterinarians

Clause 195 prohibits the sponsor or a supplier of a therapeutic product from giving a benefit to a health practitioner or veterinarian with the intention of inducing them to make favourable clinical decisions about the product. It also prohibits a health practitioner or veterinarian from accepting or asking for such a benefit.

Preparatory and supporting conduct

Clause 196 prohibits a person from agreeing or offering to carry on a supply chain activity if doing so would contravene the Bill.

Clause 197 prohibits a person, in the course of a business or undertaking, from obtaining a therapeutic product from another person if it would be unlawful for the other person to supply it.

Conduct relating to information and Regulator's powers

Clause 198 prohibits a person from including misleading information in a record that a person must keep under the Bill or altering a record to make it misleading. Misleading information means information that is false, that is misleading in a material particular, or that is misleading because of the omission of a material particular (*see clause 14*).

Clause 199 prohibits a person from giving misleading information to the Regulator or an inspector.

Clause 200 requires a person to comply with any requirement to do something that is given to them under *subpart 2 of Part 7* (regulatory powers) or *subpart 1 of Part 8* (investigative powers).

Clause 201 prohibits a person from impeding the Regulator or an inspector.

Part 7
Regulatory matters

Clause 202 ensures that this Part applies in the same way to a therapeutic product that does not have a market authorisation and its responsible manufacturer as it does to a product with a market authorisation and its sponsor.

It also enables the Regulator to exercise their regulatory powers (such as issuing recall orders or prohibited product orders) in relation to a product that has been misrepresented to be a therapeutic product when it is not.

Subpart 1—Post-market surveillance and response and compliance monitoring

Clause 203 requires the Regulator to have a post-market surveillance and response system to provide surveillance of the safety, quality, and efficacy (for medicines and APIs) or performance (for medical devices). The system must also provide for the Regulator to take action to address safety, quality, efficacy, or performance issues if they arise.

Clause 204 requires the Regulator to have systems in place to monitor compliance with the Bill by sponsors, licensees, permit holders, persons in the supply chain, and other persons to whom the Bill applies.

Subpart 2—Regulatory powers

Subpart 2 of Part 7 provides regulatory powers to enable the Regulator to perform their surveillance, response, and compliance monitoring functions (*see clause 205*).

These powers are in addition to the record-keeping, auditing, and reporting requirements that are imposed by the rules under *clause 72* (for persons in the supply chain) and *clause 143* (for sponsors), and the conditions that are imposed on licences and permits under *clause 167*.

The powers in *subpart 2* are exercisable by inspectors appointed under *clause 348* and the Regulator (who is, by definition, also an inspector).

If an inspector requires someone to do something under *subpart 2*, *clause 200* makes it an offence to fail to comply.

The exercise of powers for investigating suspected offences and other enforcement purposes is covered separately in *subpart 1 of Part 8*.

Clause 206 allows an inspector to require a sponsor, licensee or permit holder, person in the supply chain, or other person listed in that clause to give the Regulator any information the Regulator reasonably needs for regulatory purposes.

A person can be required to obtain or compile information for the purposes of giving it to the Regulator, but only when that is reasonable.

A person can be required to give personal information, but only if the information required by the Regulator could not reasonably be obtained without the personal information being disclosed.

Clause 207 gives an inspector powers in relation to sampling and testing products. The sponsor of a product can be required to take samples of the product and either have them tested and give the test results to the Regulator, or give the sample to the Regulator for testing.

In the case of a device that produces an output (such as an x-ray machine), the inspector can require the sponsor to operate the device to produce a sample output and to give that to the Regulator.

The testing must be done by a recognised testing entity. *Clause 350* provides for the Regulator to designate recognised testing entities. The Regulator can only designate an entity if satisfied of their independence and competence and that they have protections in place to maintain the confidentiality of information relating to products they test.

If a sample is taken from imported products that are still under the control of Customs, *clause 212* allows the Regulator to direct Customs to detain the products while the testing is carried out.

Clause 208 allows an inspector, for regulatory purposes, to enter a place where a supply chain activity is being carried on or where an activity to which a a licence or permit relates is being done.

However, if the place is a home, a marae or associated building, or a consultation or treatment room that is in use, an inspector may only enter with consent or under a search warrant, and must take into account the matters set out in *clause 209*.

The process for obtaining a warrant is set out in the Search and Surveillance Act 2012.

Having entered the place, the inspector may do any of the things listed in *clause 210*.

Clause 211 requires an inspector who is entering a place to find the person in charge of the place, identify themselves as an inspector, and inform the person of the purpose of the entry (or if they are unable to do so, to leave written notice of their entry).

Clause 212 allows Customs to detain imported products while they are tested. Section 159 of the Search and Surveillance Act 2012 allows the owner or person entitled to possession of the products to apply to the District Court for the product to be released in certain circumstances.

Clause 213 provides that this subpart does not affect the application of section 60 of the Evidence Act 2006. That clause applies if an individual is required by a person exercising a statutory power to provide specific information and the information would, if provided, be likely to incriminate the person for an offence. In those circumstances the person can refuse to provide the information.

Subpart 3—Regulatory orders

Subpart 3 of Part 7 allows the Regulator to make various orders in specific cases to address risks to personal health or public health or the exposure of any individual to a risk of death, serious injury, or serious illness.

If a person is required to comply with a regulatory order, not doing so may be an offence, civil penalty contravention, or infringement offence (*see subparts 2 to 5 of Part 8*).

Recall orders

Clause 214 allows the Regulator to make a recall order for a therapeutic product if satisfied that the continued availability of the product poses a risk to health. A recall order will usually be directed at the product's sponsor. They are required to have a

post-market surveillance and response system under *clause 142* and to comply with rules under *clause 143* about tracing and recall, so should be able to retrieve the product from the supply chain. A recall order may also impose requirements on people in the supply chain to, for example, return or dispose of the product.

Clause 215 requires a person who has been served with a recall order to comply with it.

Premises restriction orders

Clause 216 allows the Regulator to prohibit the use of a place or vehicle for carrying on a supply chain activity if satisfied that its use exposes a person to a risk of death, serious injury, or serious illness.

Clause 217 requires a person who has been served with a premises prohibition order to comply with it.

Advertising remediation orders

Clause 218 allows the Regulator to make an advertising remediation order if satisfied that an advertisement for a therapeutic product has been distributed in contravention of *clause 194*. The order may be directed at the person who distributed or caused the distribution of the advertisement (such as a sponsor who paid for the advertisement) or anyone else involved in its distribution.

Clause 219 requires a person who has been served with an advertising remediation order to comply with it.

Directions orders

Clause 220 allows the Regulator to make an order directing any person to do something specified in the order. The scope of this clause is very wide because the vast array of therapeutic products and the range of people who may be dealing with them means that there is an enormous number of scenarios in which the Regulator might need to give directions.

However, the Regulator can only make a directions order if the criteria in *clause 220(1)* are met and the order cannot remain in force for more than 12 months. Another directions order could then be made, but only if the criteria in *clause 220(1)* are still met.

Clause 221 requires a person who has been served with a directions order to comply with it.

Product moratorium orders

Clause 222 allows the Regulator to make a product moratorium order that prohibits people carrying on supply chain activities with the product or advertising or recommending it. Such an order can only be made if the Regulator is satisfied that the risks associated with the product are such that it is appropriate to remove it from the supply chain or limit its availability while the Regulator evaluates the product and takes any other appropriate action to manage those risks.

The other actions that the Regulator might take include:

- doing further evaluation of the product to determine whether varying or cancelling its market authorisation is appropriate:
- making rules for the purposes of *clause 72 or 143*:
- recommending that regulations be made declaring it to be a prohibited product or to limit its off-label use:
- investigating whether the risks posed by the product are the result of unlawful conduct.

Clause 223 sets out who must comply with a product moratorium order.

Prohibited product order

Clause 224 allows the Regulator to make a prohibited product order in relation to a prohibited product.

The regulations may declare a therapeutic product to be a prohibited product if it exposes any individual to a risk of death, serious injury, or serious illness (*see clause 33*). *Clause 74* prohibits anyone from carrying on any supply chain activity with a prohibited product or from acquiring it for the purposes of doing so.

A prohibited product order gives the Regulator the ability to remove any of the product from the supply chain.

Clause 225 requires a person who has been served with a product prohibition order to comply with it.

Oversupplied persons

Clause 226 gives the Regulator powers in relation to persons who are addicted or habituated to a prescription medicine or pharmacist medicine or who have obtained more of those medicines than is reasonably necessary for their own therapeutic purposes. These powers can be exercised only by the Regulator personally on the advice of a medical practitioner or by a medical practitioner to whom that power has been delegated.

Clause 227 allows the Regulator to make a medicine access limitation order in relation to an oversupplied person that prohibits anyone supplying or prescribing specified medicines for the person and prohibits the person obtaining them. The order can allow the product to be supplied or prescribed for the person in specified circumstances, such as when there is a genuine therapeutic reason for the person to have them.

Clause 228 sets out who must comply with a medicine access limitation order.

Clause 229 allows the Regulator to make a statement about an oversupplied person for the purpose of limiting the supply of medicines to them and to assist in the treatment of the person's addiction or habit.

The Regulator may disclose the statement to the persons listed in *clause 229(8)* but only for the purposes set out in *clause 229(1)*. The Regulator must not disclose it to anyone else or for any other reason.

The person who is the subject of the statement may make a complaint under the Privacy Act 2020 if it is disclosed inappropriately.

All regulatory orders

Clauses 230 to 235 set out general procedural and administrative matters relating to all regulatory orders, including the requirement for the Regulator to give affected persons an opportunity to comment before an order is made and in relation to the variation and revocation of the orders.

Subpart 4—Public safety announcements

Clause 236 allows the Regulator to make statements relating to therapeutic products for the purpose of protecting, promoting, and improving personal health or public health.

Such a statement is not an advertisement even if it promotes a therapeutic product (*see clause 193*).

No proceedings can be brought in respect of a statement made under this clause in good faith.

The clause also applies to the chief executive if they make such a statement in the course of exercising their powers under this Act.

Subpart 5—Official statements for exports

Clause 237 allows the Regulator to issue an official statement about a therapeutic product that is to be exported certifying as to any of the matters listed in this clause. The purpose of an official statement is to provide confirmation from the Regulator to the overseas importer and relevant authorities in the importing country that the product is what it is represented to be and meets the New Zealand requirements for it to be exported.

Part 8
Enforcement

Clause 238 ensures that this Part applies in the same way to a therapeutic product that does not have a market authorisation and its responsible manufacturer as it does to a product with a market authorisation and its sponsor.

It also enables the Regulator to exercise their investigative powers in relation to a product that has been misrepresented to be a therapeutic product when it is not.

Subpart 1—Investigative powers

Subpart 1 of Part 8 gives the Regulator investigative powers to enable them to investigate and obtain evidence of noncompliance with the Bill and perform their compliance functions.

If a person is given a requirement under *subpart 1* to do something, *clause 200* makes it an offence to fail to comply.

Clause 240 allows the Regulator to authorise an inspector to enter and search a specific place if the Regulator reasonably suspects that a person has contravened, is contravening, or will contravene the Bill and that the search will find evidential material (that is, evidence of the contravention, or anything else of relevance to the investigation of the contravention).

The inspector may enter and search the place with the consent of the occupier or under a search warrant.

The provisions of the Search and Surveillance Act 2012 relating to search, surveillance, and inspection powers and production orders apply to a search under this clause. Sections 118 and 119 of that Act don't apply as they relate to powers to detain or arrest people, which inspectors do not have power to do.

Clause 241 provides for search warrants. It allows an issuing officer (usually a judge) to grant a warrant if satisfied that there are reasonable grounds to suspect that a person has contravened, is contravening, or will contravene the Bill and that the search will find evidential material.

Clause 242 allows an inspector who is exercising a power under *subpart 2 of Part 7* (regulatory powers) and finds evidence of a contravention of the Bill to carry on exercising that power. This means that an inspector who has entered a place for regulatory purposes under *clause 208* and finds evidence of an offence does not have to leave the place, get a search warrant, and go back again.

Clause 243 allows an inspector who finds a person contravening the Bill to require them to give their name and address. Knowing a person's name and address is necessary to be able to take any kind of enforcement action against them as even issuing an infringement notice requires a name and address.

Clause 244 provides for the destruction of seized things.

When an inspector is exercising their investigative power to enter and search a place, *clause 240* applies various provisions of the Search and Surveillance Act 2012 to the search. The applied provisions include section 110(d) of that Act, which allows an inspector to seize anything that is the subject of the search.

If prohibited products are given to the Regulator in compliance with a prohibited products order, *clause 224* allows the Regulator to seize them.

Section 242(1)(b)(v) of the Customs and Excise Act 2018 also allows Customs to seize things that they find while exercising their powers under that Act and that are evidence of the commission of an offence under the Bill.

If something is seized under these powers and the Regulator is satisfied of any of the matters listed in *clause 244(1)(b)*, section 160 of the Search and Surveillance Act 2012 applies to enable the Regulator to destroy the thing.

Clause 245 applies to seized things that were imported into New Zealand and allows the Regulator to require the importer to remove it from New Zealand. This power is included because there are some therapeutic products that could not be safely disposed of in New Zealand.

Clause 246 allows the Regulator to recover costs incurred in dealing with seized things as a debt due to the Regulator. If a person is convicted of an offence or has a civil penalty order made against them, *clause 326* provides an alternative means of recovering those costs.

Enforcement options

Subparts 2 to 7 of Part 8 of the Bill give the Regulator a range of options for enforcing compliance with the Bill. These are:

- prosecutions for offences involving knowledge or recklessness:
- prosecutions for strict liability offence:
- civil penalty proceedings:
- infringement notices or proceedings for infringement offences:
- enforceable undertakings.

Which option to use in any particular case is a matter for the Regulator but only 1 of those options can be used. The general criminal law rules of double jeopardy prevent a person being criminally liable twice for substantially the same conduct. *Subpart 6 of Part 8* similarly prevents a person being subject to both criminal liability and a civil penalty order for substantially the same conduct.

Subpart 2—Offences involving knowledge or recklessness

Subpart 2 of Part 8 sets out a number of offences for contravening clauses of the Bill that include elements of knowledge or recklessness about the contravening conduct or the consequences of the conduct.

The defences set out in *subpart 10 of Part 8* and the evidentiary provisions in *subpart 11* are relevant for these offences.

Clause 247 makes it an offence to contravene a provision listed in this clause if doing so creates or increases a significant risk to personal health or public health and the person knows that, or is reckless as to whether, their conduct has that effect.

The maximum penalty for the offence is, for an individual, imprisonment for 5 years and a fine of $200,000, and for a company, Crown organisation, or other person who is not an individual, a fine of $1 million.

Clause 248 creates a similar offence or contravening the provisions listed in that clause but with lower maximum penalties.

Clauses 249 to 263 provide separate offences for contraventions of particular provisions of the Bill. In each case, the elements of the offences are specific to the provision being contravened.

Some of these provisions create 2 or more offences with different penalties depending on the person's state of mind or motivation. For example, *clause 250* creates 2 offences about misrepresentations—one if the person knows the representation is not true, the other when they are reckless as to whether it is true. *Clause 251* creates a separate offence depending on the person's motive.

Subpart 3—Offences not involving knowledge or recklessness

Subpart 3 of Part 8 creates 3 strict liability offences with different penalty levels for contravening the offences listed in these clauses.

In a prosecution for one of these offences, it is not necessary to prove that the defendant intended to commit the offence, or knew about the consequences of doing so, or had any other state of mind in relation to any element of the offence. Because of this, the maximum penalties for these offences are significantly less than the penalties for the offences in *subpart 2*.

The defences set out in *subpart 10 of Part 8* and the evidentiary provisions in *subpart 11* are relevant for these offences.

Subpart 4—Civil liability

Subpart 4 of Part 8 provides a mechanism for taking civil rather than criminal action against a person who contravenes the Bill. It is comparable to civil penalty regimes in other Acts.

Clause 268 provides that a person commits a civil penalty contravention if they contravene one of the provisions listed in this clause and they do so in the course of a business or undertaking or to make a commercial gain or avoid a commercial loss.

Clause 269 sets out who the parties to a contravention are and enables civil penalty orders to be made against people who are involved in a contravention or attempt to commit a contravention. This is comparable with the position under the Crimes Act 1961 for parties to a criminal offence.

Clause 270 allows a court to make a civil penalty order against a person who commits a civil penalty contravention (including a person who is a party to the contravention).

A civil penalty order is an order to pay an amount of money to the Crown.

Clause 271 sets out the maximum amount of a civil penalty. In most cases the maximum penalty is likely to be the consideration for the relevant transaction or 3 times the gain made or loss avoided.

A contravention of a provision of the Bill is only a civil penalty contravention if it occurs in the course of a business or undertaking or to make a commercial gain or avoid a commercial loss. Therefore the maximum penalties are linked to the value of the commercial benefit obtained as a result of the contravention.

As with penalties for offences, it is a matter for the court to decide how much (up to the statutory maximum) a particular person will be ordered to pay.

Clause 272 sets out matters to be taken into account by the court when it determines the amount of the civil penalty.

Clause 273 provides that the usual rules of court and rules of evidence and procedure for civil proceedings (including the standard of proof) apply to civil penalty proceedings.

Clause 274 provides that in civil penalty proceedings the person's state of mind (that is, their knowledge, intention, opinion, belief, or purpose or their reasons for that intention, opinion, belief, or purpose) is not relevant and therefore does not have to be proven.

However, the person's state of mind can be taken into account when determining the amount of the civil penalty that is imposed.

Clause 275 provides that a civil penalty is a debt due to the Crown and can be recovered by the Regulator.

Subpart 5—Infringement offences

Subpart 5 of Part 8 provides the mechanism for the Regulator to issue infringement notices in relation to a contravention of the Bill. These provisions need to be read together with the procedural requirements about infringement notices in the Summary Proceedings Act 1957 to provide the full infringement notice regime.

In broad terms the infringement notice regime allows the Regulator to issue an infringement notice to a person for an alleged infringement offence. The person can either pay the infringement fee or elect for the matter to go to court. If they don't do either, they will be issued with a reminder notice. If they still don't pay the fee or elect to go to court, the Regulator will lodge details of the matter with the Ministry of Justice who will be able to recover the amount of the infringement fee plus costs as if it were a fine imposed by a court.

If the person elects to have the matter go to court, it is in general terms dealt with according to the criminal procedure that applies to a category 1 offence under the Criminal Procedure Act 2011.

As an alternative to issuing an infringement notice, the Regulator can take court proceedings against the person for the infringement offence (*see clause 278(1)(a)*).

If the matter goes to court, the person can be ordered to pay a fine if they are found to have committed the contravention, however that is not a conviction (*see* section 375 of the Criminal Procedure Act 2011).

This infringement offences regime is the comparable to infringement offence regimes in other Acts.

Clause 277 makes it an infringement offence to contravene a provision of the Bill listed in this clause.

Clauses 278 to 283 provide the procedural requirements for how an alleged contravention of an infringement offence is to be dealt with.

Subpart 6—Interrelationship of civil penalty orders

Subpart 6 of Part 8 sets out rules to ensure that a person who contravenes a provision of the Bill cannot be subject to both a civil penalty order and criminal liability for the same conduct.

Clause 284 applies if a person's conduct constitutes a civil penalty contravention and an offence against a provision of *subpart 2 or 3 of Part 8*.

If a prosecution for the offence is commenced, civil penalty proceedings cannot be commenced (regardless of the outcome of the prosecution).

If civil penalty proceedings have been completed, a prosecution cannot be commenced.

If civil penalty proceedings have been commenced but have not been completed, a prosecution may be commenced but, if so, the civil proceedings must be dismissed.

Clause 288 ensures that evidence given in civil penalty proceedings is not admissible in later criminal proceedings.

Clause 285 applies if a person's conduct constitutes a civil penalty contravention and an infringement offence.

If proceedings are commenced for the civil penalty contravention, action cannot be taken for the infringement offence (either in court or by way of an infringement notice).

If court proceedings are commenced against the person for the infringement offence (*see clause 278(1)(a)*), proceedings cannot be commenced for the civil penalty contravention.

If an infringement notice has been issued to the person, proceedings for the civil penalty contravention can be commenced, but only if the infringement notice is withdrawn first. Under *clause 280* an infringement notice cannot be withdrawn if the person has paid the infringement fee or been fined by the court.

Clause 286 applies if a person's conduct constitutes a civil penalty contravention against *clause 268* for contraventions of 2 or more provisions listed in that clause. Proceedings may be brought in relation to 2 or more contraventions but only 1 civil penalty order can be made in relation to the conduct.

Clause 287 ensures that a person cannot be ordered to pay a civil penalty under the Bill and be ordered to pay a civil penalty or be held criminally liable under another Act for the same conduct.

Subpart 7—Enforceable undertakings

Subpart 7 of Part 8 allows the Regulator to accept an undertaking from a person in connection with an alleged contravention of a provision of the Bill. If an undertaking is accepted, as long as the person complies with it, they cannot be prosecuted, be sub-

ject to civil penalty proceedings, be issued with an infringement notice, or have infringement proceedings taken against them for the alleged contravention (*see clause 295*).

If the person does not comply with the undertaking, that is an offence (*see clauses 294 and 262*) and it allows the Regulator to take enforcement action against the person for the original contravention.

This enforceable undertaking regime is similar to enforceable undertaking regimes in other Acts.

Clause 289 gives the Regulator power to accept an undertaking and sets out the kinds of things that might be included in an undertaking. The Regulator can accept an undertaking only if satisfied that it is an appropriate way to address the alleged contravention, and cannot accept an undertaking in the circumstances listed in *clause 289(4)*.

Clause 290 sets out when the undertaking becomes enforceable and when it ceases to be in force.

Clause 291 requires the Regulator to make undertakings publicly available. *Clause 373* sets out the public availability requirements.

Clause 292 allows a person who has given an undertaking to withdraw it with the consent of the Regulator.

Clause 293 allows the Regulator to vary an undertaking on application by the person who gave it.

Clause 294 requires a person who gives an undertaking to comply with it. *Clause 262* makes it an offence to fail to do so.

Clause 295 provides that a person who gives an undertaking cannot be subject to criminal or civil penalty proceedings for the alleged contravention while the undertaking is in force or at any later time if they have complied with the undertaking.

If an undertaking ceases to be in force without being complied with (for example, because it is discharged by a court) the Regulator can take criminal or civil proceedings taken against the person for the original contravention.

Clause 296 allows the District Court to discharge the undertaking or make various other orders if satisfied that a person has not complied with the undertaking or that the Regulator's acceptance of it was obtained by fraud or in bad faith.

If a person commits an offence or civil penalty contravention there are time limits for commencing criminal or civil penalty proceedings against them. These are imposed by section 25 of the Criminal Procedure Act 2011 and Part 2 of the Limitation Act 2010.

Clause 297 extends those limitation periods so that if an undertaking is breached, proceedings for the alleged contravention can be commenced even if the usual limitation period has expired.

Subpart 8—Enforcement against the Crown

Clause 6 provides that the Bill binds the Crown. Most importantly, it provides that a Crown organisation is treated as a separate person so can be a sponsor, licensee, or permit holders in the same way as any other person. Crown organisation is defined in section 4 of the Crown Organisations (Criminal Liability) Act 2002 and includes government departments, Crown entities, and government-related organisations such as the Māori Health Authority, Police, and Defence Force.

Clause 298 provides that the Bill can be enforced against the Crown in the ways set out in *subpart 8 of Part 8*.

Clause 299 allows a Crown organisation to be prosecuted for an offence listed in *Schedule 2* or an offence in the regulations that the regulations say is a Crown-enforceable offence.

Clause 300 similarly allows an infringement notice to be issued to a Crown organisation for an infringement offence listed in *Schedule 2* or an infringement offence in the regulations that the regulations say is a Crown-enforceable infringement offence.

Clause 301 provides that civil penalty orders cannot be made against an instrument of the Crown (whether or not it is a Crown organisation).

Clause 302 allows injunctions to be made against a Crown organisation (*also see clause 322*).

Clause 303 allows the Regulator to accept a enforceable undertaking from a Crown organisation.

Clause 304 provides that if a Crown organisation is a sponsor, licensee, or permit holder, the Regulator may perform or exercise their functions and powers in the same way as they would for any other sponsor, licensee, or permit holder.

Clause 305 provides that when the Bill allows the Regulator to recover an unpaid amount as a debt, that does not apply if the amount is payable by the Crown or a Crown organisation. This is because such an action would amount to the Crown suing itself.

However, that does not affect any other consequences that might result from the non-payment (such as cancellation of a product's market authorisation if a Crown organisation sponsor does not pay a levy).

Subpart 9—Attribution of liability

Clause 306 attributes the conduct of a senior manager, worker, or agent (if they are acting within the scope of their authority) to the person they work for (**person B**). If that conduct contravenes a provision of the Bill, person B is taken to have also committed the contravention.

There is a defence for person B if they could not reasonably be expected to have known of the contravention or took all reasonable steps to ensure that the conduct did not occur.

Clause 307 applies if a person who is not an individual (usually a company) is being prosecuted for an offence and an element of the offence is that the person had a particular state of mind (for example, that they knew something, or intended something to happen). In that case, it is sufficient to show that a senior manager, a worker, or an agent of the company acting within the scope of their authority had that state of mind.

Clause 308 is the opposite of *clause 306*, but limited to senior managers. If a person who is not an individual (usually a company) contravenes a provision of the Bill, the company's senior managers are taken to have also committed the offence.

There is an equivalent defence for the senior manager if they could not reasonably be expected to have known of the contravention or took all reasonable steps to ensure that the conduct did not occur.

Subpart 10—Defences

Subpart 10 of Part 8 provides defences that apply in criminal and civil proceedings against a person for a contravention of the Bill. These are in addition to any defences that apply under other Acts (such as the Crimes Act 1961) or at common law.

If proceedings are being taken against a person in reliance on the attribution of liability provisions, the availability of the defences in *subpart 10* is limited, but there are separate defences in *clauses 306 and 308*.

Clause 310 provides a defence if the defendant took all reasonable steps to ensure that the conduct constituting the contravention did not occur and to mitigate the adverse effects of the conduct.

Clause 311 provides a defence if the contravention was due to the defendant's reliance on information given to them by another person and it was reasonable for them to rely on that information. For example, if a retailer sells a therapeutic product that does not have a market authorisation because they were relying on information from the manufacturer that the product did have a market authorisation, the retailer may have a defence under this clause.

Clause 312 provides a defence if the conduct constituting the offence was necessary to prevent the death or very serious injury or illness of any individual and was reasonable and the defendant took all reasonable steps to mitigate any adverse effects of the conduct.

Subpart 11—Evidentiary matters

Clause 313 applies if the elements of an offence include that a person's conduct creates or increases a significant risk to personal health or public (such as *clause 247*) or exposes any individual to a risk of death, serious injury, or serious illness (such as *clause 259*). In a prosecution for such an offence, it is not necessary to prove that any specific individual was exposed to that risk.

Clause 314 provides that in a prosecution for a contravention of *clause 70* (supplying a prescription medicine without a prescription) it is not necessary to prove that the person knew it was a prescription medicine.

Clause 315 relates to contraventions of *clauses 180 and 181* which involve conduct that is intended to, or might be expected to, induce a health practitioner or veterinarian to act unprofessionally. In a prosecution for an offence for a contravention of those clauses, it is not necessary to prove that a health practitioner or veterinarian did act unprofessionally.

Clause 316 relate to contraventions of *clause 195(1)*, which involves improperly inducing a health practitioner or veterinarian to make a favourable clinical decision. In a prosecution for an offence for a contravention of that clause, it is not necessary to show that a health practitioner or veterinarian was induced to make, or had made, such a decision.

Clauses 317 and 318 relate to offences for contravening various regulatory orders. In a prosecution for an offence for such a contravention the order is taken to be prima facie evidence of the matters referred to in those clauses, which are matters about which the Regulator has to be satisfied before making the order.

Clause 319 provides that in proceedings under the Bill, certain information on a label on a package is presumed to be correct unless the contrary is proved.

Clause 320 provides that if a sample of a therapeutic product is taken and tested by a recognised tester and in accordance with an approved sampling protocol, the sample is presumed to be a representative sample of the quantity of the product from which it was taken. For example, if a sample is taken from a particular production run in a manufacturing facility, it would be presumed to be representative of all the therapeutic products produced in that production run.

Clause 321 provides that in civil proceedings a certificate of a recognised tester is proof of the matters set out in it unless the contrary is proved. However, such a certificate can only be used in evidence if *clause 321(2)* is complied with.

Subpart 12—Miscellaneous matters

Clause 322 allows a court, on application by the Regulator, to grant injunctions restraining a person from engaging in conduct that would contravene a provision of the Bill.

Clause 323 allows a court that is sentencing or making an order against a person for a contravention of the Bill to also make orders under any of *clauses 324 to 328* if the court thinks it is appropriate to do so. The order may be made as well as, or instead of, any other penalty that might be imposed on the person.

Clauses 324 and 325 allow an order to be made cancelling or suspending a licence or permit, or cancelling a market authorisation if the defendant is a licensee, permit holder, sponsor, or a senior manager who is subject to proceedings under the attribution of liability provisions.

Clause 326 allows the court to order the defendant to pay the Regulator's costs incurred in mitigating the risk resulting from the defendant's conduct or in dealing with therapeutic products or other things relevant to the contravention.

Clause 327 provides that if the conduct that is the subject of the proceedings involves the use of identification, labelling, packages, or advertisements for a therapeutic product, the court to may makes orders relating the defendant's future use of those things.

Clause 328 allows the court to make orders about forfeiture or disposal of therapeutic products that are the subject of the proceedings and things related to them.

Clause 329 requires a court registrar to notify relevant people or bodies about the outcome of proceedings in the circumstances referred to in that clause.

Part 9
Regulator

Subpart 1—Therapeutic Products Regulator

Clause 330 establishes the Therapeutic Products Regulator as a statutory office. The chief executive of the Ministry appoints the person to hold the office.

Clauses 331 and 332 set out the objectives and functions of the Regulator.

Clause 333 requires the Regulator to act independently of the chief executive and Minister, although they are subject to any general policy directions given by the Minister.

It requires the Regulator to have arrangements in place to avoid or manage conflicts or interest. It also requires them to ensure they have capacity and capability to give effect to the principles of te Tiriti o Waitangi/the Treaty of Waitangi and take account of mātauranga Māori and Māori perspectives in relation to therapeutic products.

Clause 334 requires the Regulator to have a regulatory strategy that sets out how they will perform their functions and exercise their powers. The strategy must be reviewed at least every 3 years and must be publicly available.

Subpart 2—Cost recovery

Clauses 335 to 342 provide for the recovery of the costs of administering the Bill to the extent that they are not met by money appropriated by Parliament.

The Regulator, chief executive of the Ministry, and Minister are required to take reasonable steps to ensure those costs are recovered in a way that is equitable, efficient, justifiable, and transparent.

Clauses 337 to 340 provide for the regulations to set fees and levies. *Clause 338* allows for a variety of methods of setting fees and levies and the Legislation Act 2019 allows the regulations to set different fees and levies for different circumstances.

Clause 341 provides for fees and levies to be payable to the Regulator and for the Regulator to recover any unpaid amounts.

Clause 342 requires the Regulator to review the levels and methods of cost recovery at least once every 3 years and to make the results of the review publicly available.

Subpart 3—Information

Clause 343 allows the Regulator to share information with regulatory entities, overseas regulators, and overseas organisations (which includes bodies such as the World Health Organisation) for the purpose of assisting them in performing their functions or exercising their powers. However, the Regulator must not do so unless satisfied that the recipient has appropriate protections in place to protect confidential and personal information.

Clause 344 provides for Customs to share with the Regulator information they have that might assist the Regulator.

Clause 345 limits the circumstances in which the Regulator, an inspector, a recognised testing entity, or a person who works for the Regulator or testing entity can disclose information. *Clause 263* makes it an offence to disclose information knowing that, or reckless as to whether, doing so is unlawful or otherwise in bad faith.

Subpart 4—Decision making and exercise of powers

Clause 346 allows the Regulator to rely on reports, assessments, or decisions made by, or information received from, overseas regulators, overseas organisations, and other entities that the Regulator is satisfied have relevant knowledge and expertise.

Clause 347 allows the Regulator to establish advisory committees.

Clause 348 provides for the Regulator to appoint inspectors for the purposes of *subpart 2 of Part 7* (regulatory powers) and *subpart 1 of Part 8* (investigative powers).

Clause 349 requires that each inspector be issued with an ID card, which they must produce on request when they are exercising their powers.

Clause 350 provides for the Regulator to designate recognised testing entities and recognised testers who are responsible for sampling and testing products as part of the Regulator's regulatory and investigative powers.

Clause 351 allows the Regulator to delegate their functions and powers.

Clauses 352 and 353 allow the Regulator to arrange for the use of automated electronic systems to carry out actions that are part of performing their functions or exercising their powers under the Bill. As an example, it is intended that this power will be used by the Regulator to set up an online process for applying for and issuing market authorisations for NHPs.

Anything done by an automated system is taken to have been done by the Regulator and the Bill applies accordingly. For example, if an automated system refuses to issue a market authorisation for an NHP, the decision is a decision of the Regulator so can be reviewed under *subpart 5 of Part 9*. If the system decides to issue a market authorisation, it is a market authorisation issued by the Regulator under *clause 123*, so can have conditions imposed on it and could be cancelled in the same way as any other market authorisation.

Clause 354 explains what is required when a provision of the Bill requires the Regulator to give someone an opportunity to comment before a power is exercised.

Clause 355 explains what is required when a provision of the Bill requires the Regulator to notify a person of a decision of the Regulator.

Clause 356 allows the Regulator to act on requests from overseas regulators or overseas organisations to assist them in performing their functions or exercising their powers. Overseas regulators and overseas organisations usually provide similar assistance in response to requests from New Zealand.

Subpart 5—Review of Regulator's decisions

Subpart 5 of Part 9 provides for the review of decisions of the Regulator made under the provisions listed in *Schedule 3*. This includes decisions made by a delegate and decisions made by an automated system, both of which take effect as decisions of the Regulator.

Clause 357 provides that a person listed in *Schedule 3* (the applicant, sponsor, licensee, or permit holder, as the case requires) may apply for a review of a decision.

Clause 358 requires the Regulator to convene a review panel of at least 3 suitably qualified and independent persons.

Clause 359 requires the review panel to act independently, and in accordance with the principles of natural justice and any procedural requirements in the regulations.

Clause 360 requires the panel to either confirm the original decision of the Regulator or set aside that decision and refer the matter back to the Regulator for them to make a new decision. The review panel cannot make its own decision.

Clause 361 allows the applicant for review to appeal to the District Court against the decision of the review panel or, if the matter is referred back to the Regulator, the Regulator's new decision.

Clause 362 provides that seeking a review under this subpart does not affect anyone's right to commence proceedings in any court or tribunal. However, if other proceedings are commenced, the review proceedings are stayed until the other proceedings are completed.

Part 10
Miscellaneous

Subpart 1—Therapeutic products register

Clause 363 requires the Regulator to keep a publicly available register of all therapeutic products, licences, and permits.

Subpart 2—Applications, notices etc

Clause 364 to 371 set out procedural matters relating to applications to the Regulator for the purposes of the Bill.

Clause 372 sets out the procedural requirements for a person who must notify the Regulator about something.

Clause 373 sets out what the Regulator must do if a provision of the Bill requires them to make a document or information publicly available.

This clause does not apply to documents that are secondary legislation, such as the rules. The publication requirements for them are imposed by the Legislation Act 2019 (*see* the notes below about *clause 377*).

Clause 374 provides the service requirements for documents that have to be served on someone (such as regulatory orders) to be set out in regulations. Having these requirements in the regulations will allow them to be updated as methods of communication change.

Subpart 3—Regulations, rules, Regulator's notices, and exemptions

Clause 375 provides for the regulations to be made providing for anything that the Bill says must or may be provided for by regulations.

The regulations can also set criteria or other requirements that must be applied or complied with by the Regulator in making the rules or a Regulator's notice.

The Minister must not recommend that regulations be made unless they are satisfied that the proposed regulations are appropriate and proportionate having regard to the likely benefits of, and risks associated with, the therapeutic products to which they will apply.

Regulations are secondary legislation and will be published on the legislation website, presented to the House of Representatives, and be disallowable.

Clause 376 provides for regulations about offences.

The regulations will set out the infringement fee and fine for the infringement offence in *clause 277* for contraventions of provisions in the Bill.

The regulations can also make contravening a provision of the regulations an offence.

Clause 377 allows the Regulator to make rules providing for anything that the Bill says must or may be provided for by rules. It requires the Regulator to be satisfied that proposed rules are appropriate and proportionate having regard to the likely benefits of, and risks associated with, the therapeutic products to which they will apply. In making the rules the Regulator must apply any criteria in the regulations and comply with any other requirements in the regulations.

Rules are secondary legislation and must be published by the Regulator in accordance with the Legislation (Publication) Regulations 2021. Those regulations require the rules to be published on the Regulator's website and notified in the *Gazette*. The rules will be presented to the House of Representatives and be disallowable.

Clause 378 allows the Regulator to make notices providing for anything that the Bill says must or may be provided for by Regulator's notice. As with the rules, the Regulator must be satisfied that a proposed notice is appropriate and proportionate having regard to the likely benefits of, and risks associated with, the products to which it will apply. In making a notice the Regulator must apply any criteria, and comply with any other requirements, in the regulations.

Regulator's notices are not secondary legislation so *clause 378* provides for their publication, commencement, and duration.

Clause 379 allows the Regulator to exempt a specific therapeutic product or other thing, or a class of products or things, from the application of any provision of the Bill or to exempt a class of persons from compliance with any provision of the Bill.

The Regulator cannot exempt a specific person from the application of a provision of the Bill. A person who wishes to be able to do something that a provision of the Bill prohibits will need to obtain a permit under *Part 5*. That Part contains criteria and procedures for granting permits, and provisions about their effect, duration, variation, suspension, and cancellation which would be undermined if a person could obtain an exemption rather than a permit. There are also obligations on permit holders (such as to comply with rules under *clause 72*) that would not apply to a person who held an exemption.

Exemptions are secondary legislation and must be published by the Regulator in accordance with the Legislation (Publication) Regulations 2021, and will be presented to the House of Representatives and be disallowable.

Clause 380 requires the Regulator to carry out consultation with affected persons before regulations, rules, a Regulator's notice, or an exemption are made.

Clause 381 modifies the application of sections 63 to 66 and Schedule 2 of the Legislation Act 2019 (which relate to incorporation of material into secondary legislation by reference) so that the obligations they normally impose on the chief executive of the agency that administers an Act are instead imposed on the Regulator.

Subpart 4—Review of Act

Clause 382 requires the Minister to review the operation of the Bill at least every 5 years. The results of the review must be made publicly available and be presented to the House of Representatives.

Part 11
Repeals, revocations, and amendments to other enactments

Subpart 1—Repeals and revocations

Clause 383 repeals the Sunscreen (Product Safety Standard) Act 2022, which will be unnecessary as sunscreen qualifies as a therapeutic product so will be regulated under this Bill.

It also repeals all the secondary legislation made under the Medicines Act 1981. That Act is not repealed because its provisions relating to pharmacy ownership are being retained (*see subpart 3 of Part 11*).

Clause 383 also revokes the Dietary Supplements Regulations 1985, which were made under the Food Act 1981 and continued temporarily under the Food Act 2014 pending new legislation regulating NHPs.

Clause 385 revokes *Part 11* once all its repeals, revocations, and amendments have taken effect.

Subpart 2—Health Practitioners Competence Assurance Act 2003

Subpart 2 of Part 11 amends the Health Practitioners Competence Assurance Act 2003 (**HPCA Act**).

Currently the Medicines Act 1981 and regulations made under it determine which classes of health practitioners are able to prescribe which classes of medicines and in what circumstances. However, as it is the responsible authorities under the HPCA Act (such as the Medical Council of New Zealand) who regulate the health professions, they are in the best position to make decisions about these matters.

Therefore, the Bill and these amendments to the HPCA Act move that function to those responsible authorities. Under the Bill, a health practitioner is allowed to carry on controlled activities with a medicine (such as prescribing or administering it) if they are a health practitioner prescriber for the medicine, that is, if their scope of practice under the HPCA Act includes prescribing the medicine. The *new sections 11A, 14A, and 14B* of the HPCA Act provide for prescribing rights to be included in the scopes of practice of the various health professions. This also provides more flexibility to change which health practitioners are able to prescribe which medicines as needs change in the future.

Subpart 3—Medicines Act 1981

Subpart 3 of Part 11 amends the Medicines Act 1981.

The Act is renamed as the Pharmacy Ownership Act 1981.

The provisions of that Act relating to pharmacy ownership, that is sections 5A, 5B, 42C, 55D to 55G, 78, 105, and 105C are retained together with the related definitions in section 2. The rest of the Act is repealed.

The pharmacy ownership provisions—

- prohibit health practitioner prescribers from holding an interest in a pharmacy business unless they have the consent of the Regulator:
- prohibit a company from holding a pharmacy licence unless it is majority owned and controlled by 1 or more pharmacists:
- prohibit a person other than a pharmacist having a pharmacy licence or holding a majority interest in a pharmacy outside a hospital:
- prohibit a person operating or holding a majority interest in more than 5 pharmacies.

Subpart 4—Other legislation

Subpart 4 of Part 11 makes the consequential amendments to various other Acts as set out in *Schedule 4*.

The amendments to the Costs in Criminal Cases Act 1967 and Crown Organisations (Criminal Liability) Act 2002 are to facilitate the enforcement of the Bill against the Crown (*see clause 6* and *subpart 8 of Part 8*).

The amendments to the Search and Surveillance Act 2012 allow for the exercise of the regulatory powers in *subpart 2 of Part 7* and investigative powers in *subpart 1 of Part 8*.

The other amendments in *Schedule 4* are minor consequential changes such as changing references to the Medicines Act 1981 to refer to the Bill and to update terminology.

It is proposed that consequential amendments to secondary legislation will be made under the secondary legislations' empowering Acts or by regulations made in reliance on section 41 of the Legislation Act 2019.

Schedules

Schedule 1 sets out transitional, savings, and related provisions for the purpose of enabling a smooth transition to the Bill. It continues most existing consents as market authorisations and allows sponsors and persons carrying on controlled activities a reasonable time to obtain any necessary market authorisations, licences, and permits.

Schedule 2 lists Crown-enforceable offences and Crown-enforceable infringement offences for the purposes of *clauses 299 and 300*.

Schedule 3 lists reviewable decisions for the purposes of *clause 357*.

Schedule 4 sets out the consequential amendments to other Acts made by *clause 423*.

Hon Andrew Little

Therapeutic Products Bill

Government Bill

Contents

The Parliament of New Zealand enacts as follows:

1 Title

This Act is the Therapeutic Products Act **2022**.

2 Commencement

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

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

(3) However, **section 384** comes into force on the day after Royal assent.

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

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 APIs 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 NHPs across their life cycle.

4 Principles guiding exercise of powers under Act

The Regulator, 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

(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 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 a therapeutic purpose (*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 pace makers), diagnostic software, and robotic surgery machines:

(c) APIs are the active ingredients of medicines so 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 67**).

(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.

(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) 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. These controls apply in addition to the requirement for products to have a market authorisation.

(2) The controlled activities, which are listed in **section 69**, 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.

What the controls are varies depending on the type of product and the circumstances in which the activity is carried on.

(3) 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 69**).

(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**). This includes 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 **section 72** 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 57**).

(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, these 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) They also monitor 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. These 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 with the Act, the Regulator has a range of tools with which to respond. These 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 the Act a person has contravened and the circumstances in which that occurred.

(8) **Subpart 6 of Part 8, section 295**, 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,—

active moiety has the meaning set out in **section 148**

adaptable device has the meaning set out in **section 25**

additive or formulation aid has the meaning set out in **section 30**

administer, in relation to a medicine or an NHP, has the meaning set out in **section 35**

advertisement has the meaning set out in **section 193**

advertising remediation order has the meaning set out in **section 218**

alleged contravention, in relation to an enforceable undertaking, has the meaning set out in **section 289**

API (which is an acronym of active pharmaceutical ingredient) has the meaning set out in **section 28**

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 126(1)(c)**)

biologic has the meaning set out in **section 32**

biologic component has the meaning set out in **section 32**

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

civil penalty has the meaning set out in **section 270**

civil penalty order means an order made under **section 270**

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

clinical trial has the meaning set out in **section 36**

complying prescription has the meaning set out in **section 53**

complying standing order has the meaning set out in **section 54**

compound has the meaning set out in **section 37**

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

controlled activity has the meaning set out in **section 69**

critical needs product has the meaning set out in **section 34**

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

custom-made device has the meaning set out in **section 25**

Customs means the New Zealand Customs Service under the Customs and Excise Act 2018 (*see also* the definition of **subject to the control of Customs**)

device production system has the meaning set out in **section 25**

directions order has the meaning set out in **section 220**

dispense has the meaning set out in **section 38**

distribute, in relation to an advertisement, has the meaning set out in **section 193**

enforceable undertaking means an undertaking that has been accepted by the Regulator under **section 289** and is in force

enforcement purposes has the meaning set out in **section 239**

ethics approval means an approval granted by an ethics approval entity

ethics approval entity means any of the following:

(a) an ethics committee established under section 92 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 has the meaning set out in **section 39**

export authorisation means a market authorisation of the kind described in **section 117(1)(c)**

export standards has the meaning set out in **section 59**

fit and proper person, *see* **section 60**

general sale medicine has the meaning set out in **section 23**

grounds to cancel, in relation to a market authorisation, has the meaning set out in **section 136**

grounds to suspend or cancel, in relation to a licence or permit, has the meaning set out in **section 169 or 170**

health benefit claim has the meaning set out in **section 61**

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 has the meaning set out in **section 40**

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

infringement fee has the meaning set out in **section 276**

infringement notice has the meaning set out in **section 276**

infringement offence has the meaning set out in **section 276**

innovative medicine application has the meaning set out in **section 148**

inspector means—

(a) a person appointed under **section 348**; or

(b) the Regulator

intended for use has the meaning set out 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 156**

licensee means the holder of a licence

limitation includes a prohibition, restriction, or condition

low concentration NHP has the meaning set out in **section 31**

major change has the meaning set out in **section 129**

manufacture has the meaning set out in **sections 41, 43, 44, 47, and 48**

manufacturer has the meaning set out in **section 41**

market authorisation means an authorisation issued by the Regulator under **section 118 or 123**

medical device has the meaning set out in **section 24**

medicine has the meaning set out in **section 22**

medicine access limitation order has the meaning set out in **section 227**

medicine that requires compounding has the meaning set out in **section 37**

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

NHP ingredient has the meaning set out in **section 30**

non-wholesale supply has the meaning set out in **section 56**

notify means to give notice in writing to a person and, if it is the Regulator being notified, in accordance with **section 372**

NZ authorisation means a standard authorisation or provisional authorisation

off-label use has the meaning set out in **section 49**

opportunity to comment has the meaning set out in **section 354**

original decision has the meaning set out in **section 358**

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 has the meaning set out in **section 226**

patient-matched device has the meaning set out in **section 25**

permit means a permit granted under **section 164**

permit holder means the holder of a permit

permitted health benefit claim has the meaning set out in **section 61**

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

person in the supply chain has the meaning set out in **section 57**

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

personalised medical device has the meaning set out in **section 25**

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 has the meaning set out in **section 23**

pharmacy activity has the meaning set out in **section 50**

pharmacy business has the meaning set out in **section 50**

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

pharmacy licence requirements has the meaning set out in **section 51**

pharmacy medicine has the meaning set out in **section 23**

pharmacy worker has the meaning set out in **section 52**

place, for the purposes of **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

premises restriction order has the meaning set out in **section 216**

prepare for administration has the meaning set out in **section 35**

prepare for use, in relation to a medical device, has the meaning set out in **section 58**

prescribe, in relation to a medicine, has the meaning set out in **section 53**

prescription has the meaning set out in **section 53**

prescription API means an API if any medicine containing the API is (or, if manufactured, would be) a prescription medicine

prescription medicine has the meaning set out 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 has the meaning set out in **section 222**

product standards has the meaning set out in **section 63**

professional body means,—

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

(b) the Veterinary Council of New Zealand

prohibited product has the meaning set out in **section 33**

prohibited product order has the meaning set out in **section 224**

protected active ingredient information has the meaning set out in **section 148**

protection period has the meaning set out in **section 148**

provisional authorisation means a market authorisation of the kind described in **section 117(1)(b)**

publicly available has the meaning set out in **section 373**

qualified, in relation to a pharmacy worker, has the meaning set out in **section 52**

recall order has the meaning set out in **section 214**

recognised NHP ingredient has the meaning set out 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 375**

Regulator means the Therapeutic Products Regulator under **section 330**

Regulator's notice means a notice made under **section 378**

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 purpose has the meaning set out in **section 205**

reportable product has the meaning set out in **section 34**

responsible manufacturer has the meaning set out in **section 42**

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

rules means rules made by the Regulator under **section 377**

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

senior manager has the meaning set out in **section 64**

software as a medical device has the meaning set out in **section 26**

special case requirement has the meaning set out in **section 65**

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 118 or 123**; or

(b) if the market authorisation has been transferred under **section 130**, the person to whom it was transferred

standard authorisation means a market authorisation of the kind described in **section 117(1)(a)**

standard health benefit claim has the meaning set out in **section 62**

standing order has the meaning set out in **section 54**

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 has the meaning set out in **section 55**

supply chain activity has the meaning set out in **section 57**

supply-restricted device has the meaning set out in **section 27**

tamper with has the meaning set out in **section 187**

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

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

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

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

use, in relation to a medical device, has the meaning set out in **section 58**

use-restricted device has the meaning set out in **section 27**

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

wholesale supply has the meaning set out in **section 56**

work has the meaning set out in **section 66**.

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 purpose

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 a therapeutic products).

Example

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

(3) However, 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 the meaning of therapeutic product

(1) The Minister must not recommend that regulations be made about a product for **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 **section 16(3)** 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 sufficiently small 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 **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 (*also see* **section 377(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 125** 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 5 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) **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 **subsection (3)**:

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

(c) **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 Personalised medical devices and device production systems

(1) Each of the following is a **personalised medical device**:

(a) an adaptable device:

(b) a patient-matched device:

(c) a custom-made device.

(2) A medical device is an **adaptable device** if it is manufactured as a standard device but is intended to be adjusted at the point of care to suit each specific patient.

(3) A medical device is a **patient-matched device** if it is manufactured using a standard production process but with each device being produced for a specific patient to match their morphology and circumstances (including a device referred to in **section 45(2)**).

(4) A medical device is a **custom-made device** if it 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 45(3)**).

(5) A **device production system** is a system (consisting of hardware, software, and the raw materials used in producing devices) intended to be used in health care settings to produce a patient-matched device at the point of care.

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 a 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 is not software as a medical device if it is intended for use as a component part of a product that is a medical device.

(5) In **subsection (4)**, the meaning of intended for use is to be determined in accordance with **section 17** read with all necessary modifications.

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

(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.

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 ingredients 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 31(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 expressions, 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 or electrolysis:

(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 microorganism, whole or extracted:

(g) a synthetic equivalent of a substance referred to in **paragraph (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 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 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

32 Biologic and biologic component

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

(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 **paragraph (a) or (b)**.

(3) However, something that is the product of something referred to in **subsection (2)(a) or (b)** is not a biologic component.

33 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 **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.

34 Reportable products and critical needs products

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

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

(a) the product is on the pharmaceutical schedule (as defined in section 4 of 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 **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

35 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 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.

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

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

(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.

37 Compound and medicine that requires compounding

Compound

(1) To **compound** a medicine means to produce a quantity of it ready for supply to a specific patient in response to a request for that supply.

(2) Compounding a medicine is part of manufacturing it (*see* **section 43**).

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 by a pharmacist 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.

38 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.

39 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 it 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 the exporter of it (as defined in section 5 of the Customs and Excise Act 2018).

40 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 it 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 the importer of it (as defined in section 5 of the Customs and Excise Act 2018).

41 Manufacture and manufacturer

(1) To **manufacture** a therapeutic product has the meaning set out in,—

(a) if it is a medicine, **section 43**:

(b) if it is a medical device, **section 44**:

(c) if it is an API, **section 47**:

(d) if it is an NHP, **section 48**.

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

(3) However, for a medical device produced using a device production system, this section is subject to **section 45**.

42 Responsible manufacturer

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

(2) In determining who is the responsible manufacturer of a therapeutic product the following are relevant considerations:

(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, for a medical device produced using a device production system, this section is subject to **section 45**.

(6) If a medical device is remanufactured, the person who is the responsible manufacturer changes (*see* **section 46**).

43 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, releasing for supply, packing, or labelling it):

(c) if it is 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 35**).

44 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, releasing for supply, packing, or labelling it):

(c) if it is 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) if it is software as a medical device or a device that includes software, do anything that is part of developing the software:

(e) if it is a remanufactured device, do anything that is part of the process of remanufacturing it (*see* **section 46**).

(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, for a medical device produced using a device production system, this section is subject to **section 45**.

Guidance note

Preparing a device for use is part of using the device (*see* **section 58**).

45 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 at the point of care 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) manufacturing the medical device includes—

(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 **sections 42 and 45**) if the system were a medical device; and

(b) to **manufacture** a device production system means doing anything that would be part of manufacturing the system (under **section 44**) if the system were a medical device.

46 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 128**.

(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 129**); 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.

47 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, releasing for supply, packing, or labelling it):

(c) if it is 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.

48 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, releasing for supply, packing, or labelling it):

(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 hydrolysis or electrolysis.

49 Off-label use

A person carrying on a controlled activity with a medicine or medical device that has a NZ 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 NZ authorisation is authorised only for its authorised indications (*see* **section 128**). Supplying, administering, or using it for a different purpose or indication, constitutes supplying, administering, or using a product that does not have a NZ 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 NZ authorisation.

50 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 81**:

(d) exporting or importing medicines or medical devices, if that is allowed by **section 79 or 80**.

(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.

51 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.

52 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.

53 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 setting out that the rest of the medicine remains to be supplied.

(7) Rules made for **subsection (2)(b)** 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.

54 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 NZ 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 **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.

55 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, 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) 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 45(2)(e)**.

56 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 it 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) it is a medicine that requires compounding, a patient-matched device, or a custom-made device; and

(b) it is supplied to 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**.

57 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**.

58 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** includes doing any of the following:

(a) to assemble it:

(b) to adjust it for a specific patient:

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

Subpart 4—Other terms

59 Export standards

(1) The rules may set out 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 NZ 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.

60 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) an offence against a law in another country that corresponds to all or part of a relevant law; or

(iii) 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 has been a senior manager of person A; or

(b) of whom person A is or has been 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 Pharmacy Ownership Act 1981:

(m) the Misuse of Drugs Act 1975:

(n) the Psychoactive Substances Act 2013:

(o) the Radiation Safety Act 2016:

(p) the Veterinarians Act 2005:

(q) any other legislation that the regulations say is a relevant law.

61 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 identified in the market authorisation; or

(b) a custom health benefit claim set out in the market authorisation.

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

Substantiation of health benefit claim

(4) A health benefit claim about an NHP may be substantiated by scientific evidence, evidence of traditional use, or both.

(5) Information about the traditional use of a product or ingredient that is in a pharmacopeia listed in the regulations is prima facie evidence of that use.

62 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 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 61(4) and (5)**).

Amendment of rules

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

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

(6) **Subsections (4) and (5)** do not limit the ability of the Regulator to amend the rules on their own initiative.

Guidance note

The procedural and administrative requirements in **sections 364 to 371** apply to an application under this section.

Decisions on applications made under this section are reviewable under **subpart 5 of Part 9**.

63 Product standards

(1) The rules may set out 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; or

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

(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 product's 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.

64 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.

65 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 medi-

cine or medical device that does not have a NZ 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 available medicine or medical device with a NZ authorisation that is suitable to meet the clinical needs of the patient (whether as an authorised indication or an off-label use); and

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

(3) For the purposes of **subsection (2)(b)**, the health practitioner or veterinarian must have regard to any criteria or requirements in the regulations.

66 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):

(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, civil penalty contravention, or infringement offence (*see* **subparts 2 to 5 of Part 8**).

67 Market authorisation required to import, supply, or export

(1) A person must not—

(a) import or supply a medicine or medical device unless it has a NZ authorisation; or

(b) export a medicine or medical device unless it has a market authorisation; or

(c) in the course of a business or undertaking, import or supply an NHP unless it has a NZ authorisation; or

(d) in the course of a business or undertaking, export an NHP unless it has a market authorisation.

(2) However, the person may do so without the product having the requisite authorisation if—

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

(b) the product is a low concentration NHP.

Guidance note

A medicine or medical device with a market authorisation is authorised only for the authorised indications (*see* **section 128**).

Subpart 2 imposes further restrictions on who can supply or export medicines, medical devices, and NHPs and how they must do so.

68 Sponsor's consent required to import product with NZ authorisation

A person must not, in the course of a business or undertaking, import a medicine, a medical device, or an NHP with a NZ 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, civil penalty contravention, or infringement offence (*see* **subparts 2 to 5 of Part 8**).

69 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 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,—

(i) manufacturing in the course of a business or undertaking:

(ii) exporting in the course of a business or undertaking:

(iii) importing a low concentration NHP in the course of a business or undertaking:

(e) carrying on a pharmacy business.

70 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.

71 Administering NHP by injection or parenteral infusion

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

72 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) record-keeping and auditing:

(k) giving information to the Regulator:

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

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

(2) Rules made for **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 **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 **subsection (1)(m)** 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 (*instead see* **section 73**).

73 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-one working for them carries on a qualifying activity unless the 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.

74 Prohibited products

(1) A person must not import, manufacture, supply, export, prescribe, administer, use on a person or 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 224 and 244**).

75 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 **section 72**).

Pharmacists

76 Pharmacist: compounding

(1) This section applies for the purposes of **section 69(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) they compound it in accordance with a complying prescription; and

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

77 Pharmacist: dispensing

(1) This section applies for the purposes of **section 69(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) if it is a prescription medicine, they dispense it in accordance with a complying prescription; and

(c) if it does not have a NZ 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 for the patient to whom it is dispensed.

78 Pharmacist: non-wholesale supply

(1) This section applies for the purposes of **sections 67 and 69(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) if it is a prescription medicine, they comply with **section 70**; and

(c) t is 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) if it is a medicine that does not have a NZ authorisation for any indications,—

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

(ii) if it is a medicine that requires compounding, it is lawfully compounded for the patient to whom it is supplied; and

(e) if it is a medical device that does not have a NZ 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 83 or 93** to supply it to the patient.

(4) They are allowed to do so without complying with **subsection (3)** it is a general sale medicine or medical device that has a NZ 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).

79 Pharmacist: exporting

(1) This section applies for the purposes of **sections 67 and 69(1) and (2)(a)(v) and (b)(iv)**.

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

(a) it is exported to a person who is ordinarily resident in New Zealand; and

(b) the pharmacist would be allowed by **section 78** to supply it by non-wholesale supply to the person if the person were in New Zealand.

80 Pharmacist: importing

(1) This section applies for the purposes of **section 67**.

(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 78**.

81 Pharmacist: wholesale supply to transfer stock

(1) This section applies for the purposes of **sections 67 and 69(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) it is supplied to another pharmacist, a health practitioner, or a veterinarian; and

(c) the pharmacist complies with—

(i) the pharmacy licence requirements; and

(ii) any requirements in the rules about that supply.

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) they comply with—

(i) the pharmacy licence requirements; and

(ii) any requirements in the rules about taking that step.

Qualified pharmacy workers

82 Qualified pharmacy worker

(1) This section applies for the purposes of **sections 67 and 69**.

(2) A pharmacy worker working in a pharmacy business is allowed to carry on an activity that **sections 76 to 80** 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 **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 78(3)(c)(ii)**, as applied by **subsection (2)** of this section, requires a determination of the appropriateness of the medicine for the patient to be made by a pharmacist, not by the pharmacy worker.

Health practitioners

83 Health practitioner: non-wholesale supply

(1) This section applies for the purposes of **sections 67 and 69(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) if it is a prescription medicine or pharmacist medicine, they are a health practitioner prescriber for the medicine; and

(b) if it is 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) if it is a medicine that requires compounding, it is lawfully compounded for that patient; and

(e) if the medicine or device does not have a NZ 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 NZ authorisation (whether supplied for an authorised indication or an off-label use).

84 Health practitioner: prescribing

(1) This section applies for the purposes of **sections 67 and 69(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) if the medicine does not have a NZ authorisation for any indications, the special case requirement is complied with; and

(e) any requirements about complying prescriptions in rules made for **section 53** are complied with.

Guidance note

A prescription is required for non-wholesale supply of a prescription medicine (*see* **section 70**). A prescription can be issued for other medicines even though it is not required.

85 Health practitioner: administering

(1) This section applies for the purposes of **sections 67 and 69(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) if it is a medicine that requires compounding, it is lawfully compounded for that patient; and

(d) if it is a medicine that does not have a NZ authorisation for any indications, the special case requirement is complied with.

Guidance note

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

86 Health practitioner: dispensing

(1) This section applies for the purposes of **section 69(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) if it is a medicine that requires compounding, it is lawfully compounded for that patient; and

(e) if it is a medicine that does not have a NZ authorisation for any indications, the special case requirement is complied with.

87 Health practitioner: exporting

(1) This section applies for the purposes of **sections 67 and 69(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.

88 Health practitioner: importing

(1) This section applies for the purposes of **section 67**.

(2) A health practitioner may import a medicine or medical device that does not have a NZ 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; and

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

89 Health practitioner: wholesale supply to transfer stock

(1) This section applies for the purposes of **sections 67 and 69(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) it is supplied to a pharmacist, another health practitioner, or a veterinarian; and

(c) the health practitioner complies with any requirements in the rules about that supply.

(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) they comply with any requirements in the rules about taking that step.

90 Health practitioner: producing medical device using device production system

(1) This section applies for the purposes of **section 45(1)**.

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

(a) 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) they comply with any requirements in the rules about producing the device.

91 Health practitioner: standing orders

(1) This section applies for the purposes of **section 69(1) and (2)(a)(x)**.

(2) A health practitioner is allowed to issue a standing order for 1 or more medicines with a NZ 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 **section 54** are complied with.

Guidance note

The controlled activities that may be included in a standing order are set out in **section 54**.

Health practitioners' staff

92 Health practitioner's staff: non-wholesale supply

(1) This section applies for the purposes of **sections 67 and 69(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 NZ authorisation.

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

(a) **section 83** 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.

Veterinarians

93 Veterinarian: non-wholesale supply

(1) This section applies for the purposes of **sections 67 and 69(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) if it is a medicine that requires compounding, it is lawfully compounded for that patient; and

(c) if it does not have a NZ 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 NZ authorisation.

94 Veterinarian: prescribing

(1) This section applies for the purposes of **sections 67 and 69(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) if the medicine does not have a NZ authorisation for any indications, the special case requirement is complied with; and

(d) any requirements about complying prescriptions in rules made for **section 53** are complied with.

Guidance note

A prescription is required for non-wholesale supply of a prescription medicine (*see* **section 70**). A prescription can be issued for other medicines even though it is not required.

95 Veterinarian: administering

(1) This section applies for the purposes of **sections 67 and 69(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) if it is a medicine that requires compounding, it is lawfully compounded for that patient; and

(c) if it is a medicine that does not have a NZ authorisation for any indications, the special case requirement is complied with.

96 Veterinarian: dispensing

(1) This section applies for the purposes of **section 69(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) if it is a medicine that requires compounding, it is lawfully compounded for that patient; and

(d) if it is a medicine that does not have a NZ authorisation for any indications, the special case requirement is complied with.

97 Veterinarian: exporting

(1) This section applies for the purposes of **sections 67 and 69(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.

98 Veterinarian: importing

(1) This section applies for the purposes of **section 67**.

(2) A veterinarian may import a medicine or medical device that does not have a NZ 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; and

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

99 Veterinarian: wholesale supply to transfer stock

(1) This section applies for the purposes of **sections 67 and 69(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) it is supplied to a pharmacist, a health practitioner, or another veterinarian; and

(c) the veterinarian complies with any requirements in the rules about that supply.

(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) the veterinarian complies with any requirements in the rules about taking that step.

100 Veterinarian: producing medical device using device production system

(1) This section applies for the purposes of **section 45(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) they comply with any requirements in the rules about producing the device.

Veterinarians' staff

101 Veterinarian's staff

(1) This section applies for the purposes of **sections 67 and 69**.

(2) A person who works for a veterinarian is allowed to supply by non-wholesale supply a pharmacy medicine with a NZ authorisation if—

(a) **section 93** 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 93** (if **subsection (2)** does not apply), or **section 95, 96, or 100** 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.

Person acting under standing order

102 Person acting under standing order

(1) This section applies for the purposes of **sections 69(1) and (2)(a)(iii), (iv), and (viii) and 70**.

(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 54**.

Downstream activities

103 Downstream supply or administration of medicine to patient

(1) This section applies for the purposes of **sections 67, 69(1) and (2)(a)(iii), (iv), and (viii) and 70**.

(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 if it is a prescription medicine, to do so without a complying prescription; and

(b) if it is 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 NZ 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.

104 Possession of prescription medicine or prescription API

(1) This section applies for the purposes of **section 69(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

105 Patient or carer importing medicine for personal use

(1) This section—

(a) applies for the purposes of **sections 67 and 68**; 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 NZ authorisation) if they comply with the personal use import conditions.

(3) If it has a NZ authorisation, they may 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) in importing the medicine, person A is not acting in the course of a business or undertaking; and

(d) either—

(i) the luggage conditions in **subsection (5)** are complied with; or

(ii) the delivery conditions in **subsection (6)** 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) the medicine is not a prescription medicine; 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 103 and 104** apply as if the medicine had been supplied in New Zealand.

(8) **Section 103(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 wasn't 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.

106 Patient or carer importing medical device for personal use

(1) This section—

(a) applies for the purposes of **section 67**; 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 NZ authorisation if—

(a) the device is imported for the purpose of its use on—

(i) person A; or

(ii) another person or an animal for whom person A is a carer; and

(b) in importing the device, person A is not acting in the course of a business or undertaking.

Personal export

107 Personal export of medicine or medical device

(1) This section—

(a) applies for the purposes of **sections 67 and 69(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, 3 months' standard supply.

(4) A reference to 3 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 3 months calculated on the basis of the recommended daily dose specified by the medicine's responsible manufacturer.

Personalised medical devices

108 Manufacture of custom-made devices

(1) This section applies for the purposes of **sections 67 and 69(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 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) they comply with any requirements in the rules about that manufacture.

(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 may export the device to the patient if the patient is ordinarily resident in New Zealand.

109 Producing medical device using device production system

(1) This section applies for the purposes of **sections 45(1)(a) and 69(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 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 90 or 100**; and

(ii) for a specific patient of that practitioner or veterinarian; and

(c) they comply with any requirements in the rules about using the system to produce the device.

(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 may export the device to the patient if the patient is ordinarily resident in New Zealand.

Sponsors of medicines and medical devices

110 Export by sponsor of medicine or medical device

(1) This section applies for the purposes of **section 69(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

111 Manufacture and export by sponsor of NHP

(1) This section applies for the purposes of **section 69(1) and (2)(d)(i) and (ii)**.

(2) The sponsor of an NHP with a market authorisation is allowed to manufacture and export it.

112 Personalised NHPs

(1) This section applies for the purposes of **sections 67 and 69(1) and (2)(d)(i) and (ii)**.

(2) An NHP practitioner is allowed to manufacture an NHP that does not have a NZ 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 product meets the product standards that apply to it; and

(g) the practitioner complies with any other requirements in the rules about manufacturing the NHP.

(3) The NHP practitioner is allowed to supply the NHP if—

(a) they supply it to the client by non-wholesale supply; and

(b) they comply with any requirements in the rules about that supply.

(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) the NHP practitioner complies with any requirements in the rules about that export.

(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 client's 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

113 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.

114 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

115 Regulations may allow controlled activities to be carried on by other persons

(1) This section applies for the purposes of **sections 45(1)(a) and 67 to 71**.

(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 the regulations say may carry on the activity or do the thing; and

(b) they comply with any requirements in the rules about doing so.

Emergency arrangements

116 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) a situation has arisen as a result of which 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

(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).

Part 4
Market authorisations for medicines, medical devices, and NHPs

Subpart 1—Market authorisations

Kinds of market authorisations

117 Kinds of market authorisations

(1) There are 3 kinds of market authorisation—

(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 under—

(a) **section 118**, if it is for a medicine or medical device; or

(b) **section 123**, if it is for an NHP.

Guidance note

A reference to a NZ authorisation means a standard authorisation or provisional authorisation.

Issuing market authorisations for medicines and medical devices

118 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 119**; and

(b) the product meets the criteria for a market authorisation of a medicine or medical device in **section 120** ; and

(c) the proposed sponsor meets the criteria for being the sponsor of a medicine or medical device in **section 121** ; 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 364 to 371** apply to an application under this section.

Decisions under this section are reviewable under **subpart 5 of Part 9**.

119 Evaluation of medicine or medical device

(1) The Regulator must evaluate the product to determine—

(a) whether the following are satisfactorily established:

(i) if it is a medicine, its safety, quality, and efficacy for its intended authorised indications; or

(ii) if it is 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, the extent of the evaluation required would likely be different for a product that currently has a provisional authorisation or that is a result of a major change being made to a product with a market authorisation than it would be for an entirely novel product.

(3) In evaluating the product, the Regulator may (without limitation) have regard the following:

(a) anything relating to,—

(i) if it is a medicine, its safety, quality, and efficacy for its intended authorised indications; or

(ii) if it is 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) if the product is a medicine, the class of medicine it will be:

(f) conditions that might be imposed on the market authorisation under **section 133**:

(g) conditions set out in the rules, product standards, or export standards that the market authorisation might disapply (*see* **section 127**):

(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 346**).

120 Criteria for market authorisation of medicine or medical device

A medicine or medical device meets the criteria for a market authorisation if the Regulator is satisfied on reasonable grounds that all of the following apply:

(a) the following are satisfactorily established:

(i) if it is a medicine, its safety, quality, and efficacy for its intended authorised indications; or

(ii) if it is 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) if the application is for an export authorisation, the product will meet any export standards that apply to it:

(e) if the application is for a provisional authorisation, it is reasonable in the circumstances to issue a market authorisation for the product (despite the Regulator not being able to determine whether the product meets the criteria for a standard authorisation):

(f) the product is not a prohibited product.

121 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 NZ 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 arranges for another person to do so:

(c) in the case of an export authorisation, the person exports the product or arrange 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.

Issuing market authorisations for NHPs

122 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 **section 364** 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 124** are met; and

(b) to make a declaration in the application that the applicant is satisfied on reasonable grounds that those criteria are met.

Guidance note

The procedural and administrative requirements in **sections 364 to 371** apply to an application under this section.

123 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 124**; and

(b) the proposed sponsor meets the criteria for being the sponsor of an NHP in **section 125**; 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 122** as prima facie evidence of the matters declared.

(3) However, this does not limit the Regulator's powers relating to assessing applications (including to request information under **section 365** or to reject the application under **section 369**).

(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 5 of Part 9**.

124 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 the product standards that apply to it:

(d) each standard health benefit claim that the sponsor proposes to make about the NHP is a claim that the rules made for **section 62** allow to be made about the NHP:

(e) any custom health benefit claim that the sponsor proposes to make about the NHP is substantiated in accordance with **section 61(4) and (5)**):

(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 377(3)** to apply or comply with when making rules for **section 62**.

125 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 NZ authorisation, the person does, or propose 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.

Content and scope of market authorisations

126 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) if the product is a medicine or medical device, the purpose or indication for which it is authorised:

(d) if the product is a medicine, whether it is a prescription, pharmacist, 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 of the standard health benefit claims 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 133**:

(m) any conditions, product standards, export standards, or other rules that are disapplied (*see* **section 127**):

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 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.

127 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 133**:

(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.

128 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 144**).

(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 144**).

129 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) may have a significant impact on,—

(i) if it is a medicine, its safety, quality, or efficacy; or

(ii) if it is a medical device, its safety, quality, or performance; or

(iii) if it is 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.

130 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 121 or 125**.

(3) If the Regulator is not satisfied, they must refuse to transfer the authorisation.

Guidance note

Decisions under this section are reviewable under **subpart 5 of Part 9**.

Duration of market authorisations

131 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) its expiry date:

(ii) the Regulator issues a standard authorisation for the product:

(c) if it is a standard authorisation or an export authorisation and specifies an expiry date, that date:

(d) if the regulations set out a maximum duration for the authorisation, the expiry of that period:

(e) the authorisation lapses under **section 132**.

132 Market authorisation lapses on death, bankruptcy, or insolvency of sponsor

A market authorisation lapses if the sponsor,—

(a) being an individual, dies or becomes bankrupt; or

(b) being 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 113**).

Conditions on market authorisations

133 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 134 or 135**.

Guidance note

Decisions under this section are reviewable under **subpart 5 of Part 9**.

Variation of market authorisations

134 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 118 to 125** apply (with any necessary modifications) to the application.

(4) In complying with **section 119**, 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 129 and 130**.

Decisions under this section are reviewable under **subpart 5 of Part 9**.

135 Variation of market authorisation by Regulator

(1) The Regulator may vary a market authorisation on their own initiative to make any of the following changes:

(a) to change the conditions to which the authorisation is subject under **section 133**:

(b) if grounds to cancel the market authorisation exist, to 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 5 of Part 9**.

Cancellation of market authorisations

136 Grounds to cancel market authorisation

There are **grounds to cancel** a market authorisation if the Regulator is satisfied on reasonable grounds that any of the following apply:

(a) if it is a medicine, its safety, quality, and efficacy for its intended authorised indications are no longer satisfactorily established:

(b) if it is a medical device, its safety, quality, and performance for its intended authorised indications are no longer satisfactorily established:

(c) if it is 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 121 or 125**:

(h) any other criteria for authorisation under **section 120 or 124** 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.

137 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 113**).

Decisions under this section are reviewable under **subpart 5 of Part 9**.

138 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 113**).

Decisions under this section are reviewable under **subpart 5 of Part 9**.

Subpart 2—Obligations of sponsors

Guidance note

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

139 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 136**).

140 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.

141 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 NZ 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.

142 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) if the product is a medicine, its safety, quality, and efficacy; or

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

(iii) if the product is 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 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.

(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 surveillance system or response system.

143 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) record-keeping and auditing:

(k) giving information or samples to the Regulator:

(l) 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 this section cannot impose qualification, training, and competency requirements for individuals who are sponsors or who work for them (*instead see* **section 73**).

(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.

144 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 372**.

145 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) if it is 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 146** that they intend to cease importing or supplying the product.

Guidance note

The requirements for notifying the Regulator are set out in **section 372**.

146 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) if it is 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 interval between the decision and when they intend to stop is less than 12 months or 6 months (as the case requires), 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 372**.

147 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

148 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, in relation to protected active ingredient information, means a period referred to in **section 149(2) or (3)** that applies to the information.

Guidance note

In relation to applications made under the Medicines Act 1981, *also see* **clause 34 of Schedule 1**.

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

(1) During a protection period for protected active ingredient information, the Regulator must not—

(a) disclose the information, unless **section 150** allows them to do so; or

(b) use the information for the purposes of determining whether to issue any other market authorisation.

(2) The first **protection period** for protected active ingredient information starts on the date on which an application for a market authorisation for the medicine is first received, and ends on the earlier of—

(a) the date that is 5 years later; and

(b) the date on which the second protection period for the information starts.

(3) The second **protection period** for protected active ingredient information starts on the date on which the Regulator issues a market authorisation in response to the application or refuses to do so, and ends on the date that is 5 years later.

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

Despite **section 149**, 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

151 What licence may allow

(1) A licence may be granted under **section 156** 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.

152 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 167**):

(i) its expiry date (*see* **section 166**):

(j) any other information required by the regulations.

(2) If, for the purposes of **section 153(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) In this section, **licensed place** means,—

(a) if the licence is a pharmacy licence, each place at, or vehicle 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

For **subsection (1)(f)**, a pharmacy licence may identify places individually or by class. It may 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 at the facility.

153 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 who 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 154**.

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 69** because the licence does not allow that. If Big Co manufactured medicine A at a different factory, they would also contravene **section 69** 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 168**) or get a separate licence to do the other thing.

154 Effect of pharmacy licence: additional provisions

(1) If a licence allows the licensee to carry on a pharmacy business,—

(a) the licence is a pharmacy licence (*see* **section 14**, definition of **pharmacy licence**); and

(b) the effect of **section 153(1)(a) and (b)** is that, subject to this section, the licensee and persons working for them may carry on the pharmacy business; and

(c) the effect of **sections 76 to 82** is that pharmacists and pharmacy workers working in the business may carry on pharmacy activities.

(2) However, despite the effect of **section 153(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, on behalf of the licensee, by an individual who is personally allowed to carry on that pharmacy activity (whether by **sections 76 to 82** 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 152(1)(d)**) that it does.

155 Effect of licence allowing products without NZ 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 NZ 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 NZ authorisation; and

(b) if the product is a medicine or medical device, its authorised indications were those set out in the licence; and

(c) if the product is 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.

156 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 157**; and

(b) the criteria for a licence in **section 158** are met; and

(c) the Regulator is satisfied that it is appropriate to grant the licence.

(3) If **subsection (2)(a) to (c)** are 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 364 to 371** apply to an application under this section.

Decisions under this section are reviewable under **subpart 5 of Part 9**.

157 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.

158 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 set out in the rules:

(b) each responsible person meets the criteria for being a responsible person in **section 159**:

(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 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 NZ 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 NZ authorisation:

(i) any other criteria in the rules.

Example

For the purposes of **subsection (1)(h)**, special circumstances might be that there is a shortage of a life-saving medicine and there is no alternative medicine with a NZ 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.

159 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

160 What permit may permit

(1) A permit may be granted under **section 164** 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 NZ 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)**.

161 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 167**):

(h) its expiry date (*see* **section 166**):

(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.

162 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.

163 Effect of permit allowing products without NZ 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 NZ 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 NZ authorisation; and

(b) if the product is a medicine or medical device, its authorised indication were those set out in the permit; and

(c) if the product is 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.

164 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 permit holder if—

(a) the criteria for a permit in **section 165** are met; and

(b) the Regulator is satisfied that it is appropriate to grant the permit.

(3) If **subsection (2)(a) and (b)** are 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 364 to 371** apply to an application under this section.

Decisions under this section are reviewable under **subpart 5 of Part 9**.

165 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 the permit allows to do something is a fit and proper person to do the thing:

(c) the permit holder and any other person who the permit allows to do something are, or will be, able to comply with this Act:

(d) everything 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 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:

(f) if the licence allows a person to import a therapeutic product that does not have a NZ 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 NZ authorisation:

(g) if the permit relates to a prohibited product, any criteria in the regulations about carrying out activities with the prohibited product:

(h) any other criteria in the rules:

(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

166 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

167 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 168**.

Guidance note

Decisions under this section are reviewable under **subpart 5 of Part 9**.

Variation of licence or permit

168 Variation of licence or permit

(1) The Regulator may vary a licence or permit (including any conditions to which it is subject under **section 167**) 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 5 of Part 9**.

Suspension and cancellation of licence or permit

169 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) any of the criteria for granting a licence in **section 158** are not met:

(b) the licensee has contravened a provision of this Act:

(c) any other person who the licence allows 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 158(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.

170 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) any of the criteria for granting a permit in **section 165** 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 the permit allows 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 licence allows a person to conduct a clinical trial, the ethics approval for the trial or the certificate referred to in **section 165(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.

171 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 5 of Part 9**.

172 Procedure to suspend or cancel

(1) The Regulator must not suspend or cancel a licence or permit under **section 171** 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.

173 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 5 of Part 9**.

174 Duration of suspension

The suspension of a licence or permit by the Regulator—

(a) takes effect when the notice under **section 171 or 173** 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 175**.

175 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 5 of Part 9**.

176 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 171 or 173** is served or at any later time set out in it.

Transfer of licence or permit

177 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 178**.

178 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 5 working days after the event occurs.

Guidance note

The requirements for notifying the Regulator are set out in **section 372**.

Subpart 4—Obligations of licensees, permit holders, and responsible persons

Guidance note

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

179 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.

180 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.

181 Licensee, permit holder, or senior manager must not induce health practitioner or veterinarian to act unprofessionally

A licensee, permit holder, or a 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.

182 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-one working for them carries on a qualifying activity unless the 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.

183 Responsible person must report noncompliance

(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) 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 the licence allows to do something.

Guidance note

The requirements for notifying the Regulator are set out in **section 372**.

184 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.

185 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) oversight of the day-to-day operation of the activities of the licensee.

(2) Rules made for this section cannot impose qualification, training, and competency requirements for responsible persons or other individuals who work for the licensee (*instead see* **section 182**).

186 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 (as defined in **section 152**) 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 **section 82(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 82**).

Part 6
Other prohibited conduct

Guidance note

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

Tampering

187 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) if the product is a medicine, its safety, quality, or efficacy:

(ii) if the product is a medical device, its safety, quality, or performance:

(iii) if the product is an NHP, its quality or safety:

(iv) in any case, how the product is used.

188 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.

189 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.

Guidance note

The requirements for notifying the Regulator are set out in **section 372**.

Misrepresentation

190 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 not a prohibited product.

191 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 if that is not the case:

(a) a sponsor:

(b) a licensee or permit holder:

(c) allowed to carry on a supply chain activity:

(d) allowed by this Act to do anything else or to do something in a particular way.

Health benefit claims

192 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 criteria in **section 125(1)(b) or (c)** for being the sponsor of the NHP.

Advertising

193 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 announcements made under **section 236**:

(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.

194 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 NZ authorisation (unless it is an API); or

(ii) outside New Zealand, the product has a market authorisation (unless it is an API); 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 distribution requirements in the regulations.

(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:

(c) it must not contain any information that is, directly or by implication, inconsistent with the product's market authorisation (unless it is an API):

(d) if it is an advertisement for a medicine or medical device, it must not promote the product, directly or by implication, for an off-label use:

(e) if it is 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) Regulations made for this section may (without limitation) relate to any of the following:

(a) the form of an advertisement:

(b) how an advertisement is distributed:

(c) to whom an advertisement is distributed.

Improper inducements to health practitioners or veterinarians

195 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

196 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.

197 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

198 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.

199 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.

200 Compliance with regulatory or investigative requirement

(1) A person who is given a requirement to do something under **subpart 2 of Part 7** (regulatory powers) or **subpart 1 of Part 8** (investigative powers), other than **section 243**, must comply with it.

(2) A person who is required under **section 243** to give their name and address or supporting evidence to an inspector must do so.

201 Impeding Regulator or inspector

A person must not impede the Regulator or an inspector in performing their functions or exercising their powers under this Act.

Part 7
Regulatory matters

202 Application of Part to products without market authorisation and misrepresented products

(1) In relation to a therapeutic product that does not have market a 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 121(1)(a) or 125(1)(a)**, that person; or

(b) if **paragraph (a)** does not apply but another manufacturer meets that criterion, that person; or

(c) if neither of **paragraphs (a) or (b)** apply, the importer of the product.

(2) If a product is misrepresented to be a therapeutic product when it is not, 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 190**.

Subpart 1—Post-market surveillance and response, and compliance monitoring

203 Post-market surveillance and response

(1) The Regulator must have in place a post-market surveillance and response system for all therapeutic products with a market authorisation or that are otherwise lawfully in the supply chain.

(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.

(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.

204 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

205 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 203**:

(b) perform their post compliance monitoring function under **section 204**:

(c) otherwise perform their functions and exercise their powers under this Act.

206 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 143**):

(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 200**).

207 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) if the product is 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 350**) 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 200**).

Sections 244 to 246 apply to things that have been seized by the Regulator.

208 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 done.

(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 209**.

(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.

209 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 208(1)**; or

(b) is the only practicable means by which an inspector can enter a place referred to in **section 208(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 entry to the restricted place only for the purposes of exercising their powers under **section 210**.

(7) In this section,—

consulting room means a room where an NHP practitioner (as defined in **section 112**) carries on consultations with 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.

210 Inspector's powers having entered place

(1) An inspector who has entered a place referred to in **section 208(1)** (under that section or **section 209**) 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 206(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 208(2)**) that they reasonably need:

(b) require any of the persons referred to in **section 206(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) However, this section does not permit the inspector to access, or require anyone to give them (or anyone else) access to, any computer system or data storage device that is not part of a therapeutic product.

(6) 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 350**).

Guidance note

A person who is required by an inspector to do something must do it (*see* **section 200**).

211 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 349 also requires an inspector to produce their identification card on request.

212 Imported consignments may be detained pending testing

(1) If an inspector exercises a power under **section 207** 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 it 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 244(1)(a)**:

(c) 20 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.

213 Privilege against self-incrimination

Nothing in this subpart affects the application of section 60 of the Evidence Act 2006.

Subpart 3—Regulatory orders

Guidance note

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

Recall orders

214 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) the removal of 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.

215 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 214(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

216 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 the use, in the course of a business or undertaking, of a specified place or vehicle for, or in relation to, the carrying on of a specified supply chain activity.

217 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

218 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 194**.

(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.

219 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

220 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.

221 Compliance with directions order

A person who has been served with a directions order by the Regulator must comply with it.

Product moratorium orders

222 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) if the product is a medicine, its safety, quality, and efficacy; or

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

(iii) if the product is 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.

223 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) if they are not a person in the supply chain, they know that the order is in force.

Prohibited product order

224 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 when it is not as if it were a prohibited product (*see also* **section 202(2)**).

Guidance note

Section 244 provides for the destruction of seized things.

225 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

226 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 227**:

(b) make a statement about the individual under **section 229**.

(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 227 and 229** may be exercised only—

(a) by the Regulator in person and after having regard to the advice of a medical practitioner; or

(b) by a medical practitioner to whom that power has been delegated by the Regulator (which delegation must be made in writing).

227 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 226(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 a specified medicine to or for the individual by a specified person in specified circumstances.

228 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.

229 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 226(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 necessary or desirable 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 necessary or desirable 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 or desirable for the purposes set out in **subsection (1)**.

(4) Except as permitted by **subsection (3)**, the Regulator must not disclose the statement without the consent of the individual.

(5) If the statement is disclosed to a notifiable person, **subsections (3) and (4)** apply to that person as if they were the Regulator.

(6) 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) or (4)**.

(7) No proceedings (whether civil or criminal), other than proceedings for judicial review or as referred to in **subsection (6)**, 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.

(8) 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) the chief executive of the Māori Health Authority:

(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 professional body:

(l) the Health and Disability Commissioner.

All regulatory orders

230 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) be made on 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.

231 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.

232 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 373**.

233 Regulatory order overrides other provisions of Act

(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.

234 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 231**.

(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 5 of Part 9**.

235 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 5 of Part 9**.

Subpart 4—Public safety announcements

236 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—

(a) include in the statement any information they think is appropriate; and

(b) publish the statement in any way they think is appropriate.

(3) 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.

(4) 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.

(5) 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 order under **section 116**).

Subpart 5—Official statements for exports

237 Official statement for export of therapeutic product

(1) The Regulator may, on application, issue an statement (an **official statement**) for a therapeutic product that is to be exported.

(2) In an official statement, the Regulator may certify as to 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 stated 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 364 to 371** apply to an application under this section.

Decisions under this section are reviewable under **subpart 5 of Part 9**.

Part 8
Enforcement

238 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 121(1)(a) or 125(1)(a)**, that person; or

(b) if **paragraph (a)** does not apply but another manufacturer meets that criterion, that person; or

(c) if neither of **paragraphs (a) or (b)** apply, the importer of the product.

(2) If a product is misrepresented to be a therapeutic product when it is not, 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 190**.

Subpart 1—Investigative powers

239 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 noncompliance or suspected noncompliance 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 268**; 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.

240 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 241**.

(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.

241 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 240(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.

242 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 240**) applies as if they were acting under a search warrant.

243 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.

(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.

A person who is required by an inspector to give their name and address or supporting evidence must do so (*see* **section 200**).

Seized things

244 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) if it is a medicine or an API, its safety, quality, or efficacy may not be acceptable:

(ii) if it is a medical device, its safety, quality, or performance may not be acceptable:

(iii) if it is an NHP, its safety or quality may not be acceptable; or

(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 245** 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) the seized thing were something possession of which 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.

245 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 244**.

246 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 245** 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 326**).

(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 or recklessness

247 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 67** (market authorisation required to import, supply, or export):

(b) **section 68** (sponsor's consent required to import product with NZ authorisation):

(c) **section 69** (controlled activity prohibited unless allowed by licence, permit, or **subpart 3**):

(d) **section 70** (non-wholesale supply of prescription medicine: prescription required):

(e) **section 71** (administering NHP by injection or parenteral infusion):

(f) **section 72** (person in supply chain must comply with rules):

(g) **section 73** (person in supply chain must comply with qualification, training, and competency requirements):

(h) **section 74** (prohibited products):

(i) **section 139** (sponsor must ensure compliance with market authorisation):

(j) **section 140** (sponsor must ensure product meets product standards):

(k) **section 141** (sponsor must ensure product meets export standards):

(l) **section 143** (sponsor must comply with rules):

(m) **section 144** (sponsor must notify Regulator of certain minor changes):

(n) **section 182** (licensee and permit holder must comply with qualification, training, and competency requirements):

(o) **section 188** (supply chain activity with tampered-with products):

(p) **section 196** (agreeing or offering to carry on supply chain activity unlawfully):

(q) **section 215** (compliance with recall order):

(r) **section 225** (compliance with prohibited product order).

248 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 179** (licensee must ensure responsible person has authority and resources):

(b) **section 180** (licensee or permit holder must ensure health practitioner or veterinarian has authority and resources):

(c) **section 185** (responsible person must comply with rules):

(d) **section 186** (pharmacy licensee must ensure pharmacy activities are carried on by persons allowed to do so):

(e) **section 219** (compliance with advertising remediation order).

249 Offences for tampering with therapeutic product

(1) A person commits an offence if—

(a) they contravene **section 187(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 187(2)**; and

(b) they do so—

(i) 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) 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.

250 Offences for misrepresentation about therapeutic product

(1) A person commits an offence if—

(a) they contravene **section 190**; and

(b) they know that the representation is not true.

(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 190**; 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.

251 Offences for holding out misrepresentation

(1) A person commits an offence if—

(a) they contravene **section 191**; 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 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 191**; and

(b) they know that the representation is not true; and

(c) they make it with intent to frustrate the administration of this Act.

(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.

252 Offence for impermissible health benefit claims about NHPs

(1) A person commits an offence if—

(a) they contravene **section 192**; and

(b) they know that, or are reckless as to whether, the claim is a permitted health benefit claim for the NHP.

(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.

253 Offences for unlawful advertising

(1) A person commits an offence if—

(a) they contravene **section 194**; 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 NZ authorisation or as 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 distribution requirements.

(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.

254 Offence for misleading information in records

(1) A person commits an offence if—

(a) they contravene **section 198**; 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.

255 Offences for misleading information to Regulator or inspector

(1) A person commits an offence if—

(a) they contravene **section 199**; 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) frustrate the administration 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 199**; 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 199**; 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.

256 Offences for noncompliance with regulatory or investigative requirement

(1) A person commits an offence if—

(a) they contravene **section 200**; and

(b) they know that they have been given the requirement.

(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 200**; and

(b) they are reckless as to whether they have been given the requirement.

(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.

257 Offences for impeding Regulator or inspector

(1) A person commits an offence if—

(a) they contravene **section 201**; and

(b) they do so with intent to impede 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 201**; and

(b) they are reckless as to whether they will impede 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.

258 Offence for noncompliance with premises restriction order

(1) A person commits an offence if—

(a) they contravene **section 217**; 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.

259 Offence for noncompliance with directions order

(1) A person commits an offence if—

(a) they contravene **section 221**; 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.

260 Offence for noncompliance with product moratorium order

(1) A person commits an offence if—

(a) they contravene **section 223**; and

(b) in doing so, they doe 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.

261 Offence for noncompliance with medicine access limitation order

(1) A person commits an offence if—

(a) they contravene **section 228(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.

262 Offences for noncompliance with enforceable undertaking

(1) A person commits an offence if—

(a) they contravene **section 294**; 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 294**; 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 294**; 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.

263 Offence for unlawful disclosure of information

(1) A person commits an offence if—

(a) they contravene **section 345**; 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

264 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 181** (licensee, permit holder, or senior manager must not induce health practitioner or veterinarian to act unprofessionally):

(b) **section 184** (protection of responsible person from retaliation):

(c) **section 195** (improper inducement to health practitioner or veterinarian).

265 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 67** (market authorisation required to import, supply, or export):

(b) **section 68** (sponsor's consent required to import product with NZ authorisation):

(c) **section 69** (controlled activity prohibited unless allowed by licence, permit, or **subpart 3**):

(d) **section 70** (non-wholesale supply of prescription medicine: prescription required):

(e) **section 71** (administering NHP by injection or parenteral infusion):

(f) **section 72** (person in supply chain must comply with rules):

(g) **section 73** (person in supply chain must comply with qualification, training, and competency requirements):

(h) **section 74** (prohibited products):

(i) **section 139** (sponsor must ensure compliance with market authorisation):

(j) **section 140** (sponsor must ensure product meets product standards):

(k) **section 141** (sponsor must ensure product meets export standards):

(l) **section 142** (sponsor must have surveillance and response system):

(m) **section 143** (sponsor must comply with rules):

(n) **section 144** (sponsor must notify Regulator of certain minor changes):

(o) **section 182** (licensee and permit holder must comply with qualification, training, and competency requirements):

(p) **section 187** (tampering with therapeutic product):

(q) **section 188** (supply chain activity with tampered-with products):

(r) **section 192** (impermissible health benefit claims about NHPs):

(s) **section 194** (advertising):

(t) **section 196** (agreeing or offering to carry on supply chain activity unlawfully):

(u) **section 198** (misleading information in records).

266 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 179** (licensee must ensure responsible person has authority and resources):

(b) **section 180** (licensee or permit holder must ensure health practitioner or veterinarian has authority and resources):

(c) **section 185** (responsible person must comply with rules):

(d) **section 186** (pharmacy licensee must ensure pharmacy activities are carried on by persons allowed to do so):

(e) **section 190** (misrepresentation about therapeutic product):

(f) **section 197** (obtaining therapeutic product when supply is unlawful):

(g) **section 199** (misleading information to Regulator or inspector):

(h) **section 200(1)** (compliance with regulatory or investigative requirement):

(i) **section 201** (impeding Regulator or inspector):

(j) **section 215** (compliance with recall order):

(k) **section 217** (compliance with premises restriction order):

(l) **section 219** (compliance with advertising remediation order):

(m) **section 221** (compliance with directions order):

(n) **section 223** (compliance with product moratorium order):

(o) **section 225** (compliance with prohibited product order):

(p) **section 228(1)** (compliance with medicine access limitation order):

(q) **section 294** (compliance with enforceable undertaking).

267 Proof of state of mind not required for strict liability offence

In proceedings against a person for an offence against **section 264, 265, or 266**, 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

268 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 68** (sponsor's consent required to import product with a NZ authorisation):

(b) **section 69** (controlled activity prohibited unless allowed by licence, permit, or **subpart 3**):

(c) **section 72** (person in supply chain must comply with rules):

(d) **section 73** (person in supply chain must comply with qualification, training, and competency requirements):

(e) **section 139** (sponsor must ensure compliance with a market authorisation):

(f) **section 140** (sponsor must ensure product meets product standards):

(g) **section 141** (sponsor must ensure product meets export standards):

(h) **section 142** (sponsor must have surveillance and response system):

(i) **section 143** (sponsor must comply with rules):

(j) **section 145** (sponsor of reportable product must notify Regulator of likely shortage):

(k) **section 146** (sponsor of reportable product must notify decision to stop supplying product):

(l) **section 179** (licensee must ensure responsible person has authority and resources):

(m) **section 180** (licensee or permit holder must ensure health practitioner or veterinarian has authority and resources):

(n) **section 181** (licensee, permit holder, or senior manager must not induce health practitioner or veterinarian to act unprofessionally):

(o) **section 182** (licensee and permit holder must comply with qualification, training, and competency requirements):

(p) **section 184** (protection of responsible person from retaliation):

(q) **section 186** (pharmacy licensee must ensure pharmacy activities are carried on by persons allowed to do so):

(r) **section 189** (notifying Regulator of suspicion of tampering):

(s) **section 190** (misrepresentation about therapeutic product):

(t) **section 191** (holding out misrepresentation):

(u) **section 192** (impermissible health benefit claims about NHPs):

(v) **section 194** (advertising):

(w) **section 195** (improper inducement to health practitioner or veterinarian):

(x) **section 196** (agreeing or offering to carry on supply chain activity unlawfully):

(y) **section 197** (obtaining therapeutic product when supply is unlawful):

(z) **section 198** (misleading information in records):

(aa) **section 199** (misleading information to Regulator or inspector):

(ab) **section 215** (compliance with recall order):

(ac) **section 219** (compliance with advertising remediation order):

(ad) **section 223** (compliance with product moratorium order):

(ae) **section 225** (compliance with prohibited product order).

269 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

270 Civil penalty order

(1) A 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 268**.

(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**).

271 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:

(c) if the person is an individual, $250,000:

(d) if the person is not an individual, $2,000,000.

272 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 occurred:

(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

273 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.

274 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 269** (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.

275 Civil penalty payable to 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

276 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 376**)

infringement notice means a notice issued under **section 279**

infringement offence means—

(a) an offence against **section 277**; or

(b) an offence against a provision of the regulations that the regulations say is an infringement offence.

277 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 67** (market authorisation required to import, supply, or export):

(b) **section 68** (sponsor's consent required to import product with NZ authorisation):

(c) **section 69** (controlled activity prohibited unless allowed by licence, permit, or **subpart 3**):

(d) **section 72** (person in supply chain must comply with rules):

(e) **section 73** (person in supply chain must comply with qualification, training, and competency requirements):

(f) **section 139** (sponsor must ensure compliance with market authorisation):

(g) **section 141** (sponsor must ensure product meets export standards):

(h) **section 142** (sponsor must have surveillance and response system):

(i) **section 143** (sponsor must comply with rules):

(j) **section 144** (sponsor must notify Regulator of certain minor changes):

(k) **section 145** (sponsor of reportable product must notify Regulator of likely shortage):

(l) **section 146** (sponsor of reportable product must notify decision to stop supplying product):

(m) **section 183** (responsible person must report noncompliance):

(n) **section 185** (responsible person must comply with rules):

(o) **section 186** (pharmacy licensee must ensure pharmacy activities are carried on by persons allowed to do so):

(p) **section 189** (notifying Regulator of suspicion of tampering):

(q) **section 190** (misrepresentation about therapeutic product):

(r) **section 192** (impermissible health benefit claims about NHPs):

(s) **section 194** (advertising):

(t) **section 196** (agreeing or offering to carry on supply chain activity unlawfully):

(u) **section 197** (obtaining therapeutic product when supply is unlawful):

(v) **section 198** (misleading information in records):

(w) **section 199** (misleading information to Regulator or inspector):

(x) **section 200(1) or (2)** (compliance with regulatory or investigative requirement):

(y) **section 219** (compliance with advertising remediation order):

(z) **section 223** (compliance with product moratorium order):

(aa) **section 225** (compliance with prohibited product order)

(ab) **section 228(2)** (compliance with medicine access limitation order).

278 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 279**.

(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.

279 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.

280 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 278(1)(a) or (b)** against the person to whom the notice was issued in respect of the same matter.

281 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.

282 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 business 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.

283 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

284 Civil penalty contravention and offence

(1) This section applies if—

(a) a person's conduct constitutes a civil penalty contravention against **section 268**; 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 376(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 dismissed.

285 Civil penalty contravention and infringement offence

(1) This section applies if—

(a) a person's conduct constitutes a civil penalty contravention against **section 268**; 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 278(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 280**.

286 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 268** 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 penalty order may be made against the person in relation to the conduct.

287 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.

288 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.

Subpart 7—Enforceable undertakings

289 Regulator may accept undertaking

(1) The Regulator may, on application, accept an undertaking given by a 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) in 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, in 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.

290 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 292**; or

(c) it is discharged by a court (*see* **section 249**).

291 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 373**.

292 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.

293 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.

294 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 of Part 8**).

295 No proceedings for alleged contravention if undertaking complied with

(1) If a person has given an enforceable undertaking, 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.

296 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 it is 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.

297 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

298 Enforcement of Act against the Crown

This Act may be enforced against the Crown only in the manner provided in this subpart.

299 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 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 376(1)** that the regulations say is a Crown-enforceable offence.

300 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 278(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 to the Crown).

(3) In this section, a **Crown-enforceable infringement offence** means—

(a) an infringement offence against **section 277** 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.

301 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 in that person's personal capacity (including on reliance on **section 308**).

(3) However, a person referred to in **subsection (2)** may be immune from liability (for example, under section 104 of the Public Service Act 2020 or section 121 of the Crown Entities Act 2004).

302 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).

303 Enforceable undertakings

The Regulator may, under **section 289**, 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).

304 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.

305 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 nonpayment.

Example

An example of a consequence that might result from nonpayment is the Regulator cancelling a market authorisation under which a Crown organisation is the sponsor for nonpayment of a levy that is payable by sponsors.

Subpart 9—Attribution of liability

306 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.

307 State of mind of senior managers, workers, or 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 376(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.

308 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 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

309 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 376(1)**; and

(b) in proceedings against a person for a civil penalty contravention against **section 268**; and

(c) in proceedings against a person for an infringement offence in accordance with section 21 of the Summary Proceedings Act 1957.

(2) In proceedings against a person in reliance on **section 306 or 308** (person B in that section), the person has a defence under a provision of this subpart only if person A in **section 306 or 308** would have a defence under that provision.

Guidance note

Note that **sections 306 and 308** contain separate defences for person B.

310 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.

311 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)**.

312 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 offence 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.

Subpart 11—Evidentiary matters

313 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.

314 Proof of knowledge of class of medicine not required

In a prosecution of a person for an offence against **section 247** for a contravention of **section 70** (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.

315 Proof of unprofessional conduct not required

In proceedings against a person for a contravention of—

(a) **section 180** (licensee or permit holder must ensure health practitioner or veterinarian has authority and resources); or

(b) **section 181** (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.

316 Proof of favourable clinical decision not required

In proceedings against a person for a contravention of **section 195(1)** (improper inducement to health practitioner or veterinarian), it is no 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 prima facie evidence

317 Prima facie evidence of risk

(1) In a prosecution of a person for an offence against **section 247** for a contravention of **section 215 or 225** the recall order or prohibited product order is prima facie 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 258 or 259** the premises restriction order or directions order is prima facie 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 260** the product moratorium order is prima facie 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.

318 Prima facie evidence of being oversupplied person

In a prosecution of a person for an offence against **section 261** for a contravention of **section 228(1)**, the medicine access limitation order is prima facie evidence that the person who is the subject of the order is an oversupplied person.

Presumptions

319 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, **subsections (1) and (2)** do not apply if the contrary is proved.

320 Presumptions about samples

(1) This section applies in relation to a sample taken from an identified quantity of therapeutic products if the sample—

(a) is taken by a recognised tester at a recognised testing entity (as defined in **section 350**); 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 products from which it was taken unless the contrary is proved.

321 Evidence of testing

(1) In civil penalty proceedings, a certificate of testing issued by a recognised tester (as defined in **section 350**) is proof of the matters set out in it unless the contrary is proved.

(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 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

322 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

323 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 270**; 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 324 to 328** 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.

324 Court may 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 308**.

(2) The court may, by order, cancel or suspend the licence or permit if satisfied that any of the grounds to suspend or cancel it listed in **section 169 or 170** exist.

(3) Before doing so, the court must give the Regulator an opportunity to make submissions to the court on the matter.

325 Court may 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 308**.

(2) The court may, by order, cancel the product's market authorisation if satisfied that any of the grounds to cancel it listed in **section 136** exist.

(3) Before doing so, the court must give the Regulator an opportunity to make submissions to the court on the matter.

326 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 246**) 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.

327 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 is appropriate in relation to the defendant's future use of identification, labelling, packages, or advertisements for therapeutic products.

(3) Before doing so, the court must give the Regulator an opportunity to make submissions to the court on the matter.

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.

328 Court may make orders about forfeiture and seizure

(1) This section applies to a therapeutic product in relation to which the contravention the subject of the proceedings was committed.

(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

329 Notice of court orders

(1) If a court makes an order under **section 324 to 328**, 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 professional 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

330 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 appropriate experience and expertise 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).

331 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.

332 Functions of Regulator

(1) 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 60**):

(f) to engage and co-operate with relevant government, local government, and non-government entities, including by sharing information under **section 343**:

(g) to engage and co-operate with overseas regulators and overseas organisations, including—

(i) by sharing information under **section 343**; 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 346**):

(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 237**:

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.

(2) This section does not permit the Regulator to disclose information contrary to any restriction on the disclosure of the information (whether in this Act, the Privacy Act 2020, or otherwise).

333 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 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.

334 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 373**.

Subpart 2—Cost recovery

335 Recovery of costs

(1) The Regulator, chief executive of the Ministry, and 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.

336 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.

337 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 amount of a fee or levy or the method by which it is to be calculated (*see* **section 338**):

(b) who is liable to pay a fee or levy:

(c) when a fee or levy must be paid:

(d) how a fee or levy may be recovered (but without limiting **section 341**):

(e) 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 376**).

(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.

338 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 does either or both of the following:

(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).

339 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 380(3)(a)(i)** substantially agree with the increase or imposition.

340 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 336** have been taken into account in determining the 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 338**; and

(c) if applicable, the regulations comply with **section 339**; and

(d) the fee or levy is otherwise appropriate and proportionate.

(2) For the purposes of **section 380**, 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).

341 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 nonpayment.

Example

An example of a consequence that might result from nonpayment is the Regulator cancelling a market authorisation under which a person is the sponsor for nonpayment of a levy that is payable by sponsors.

342 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 373**.

Subpart 3—Information

343 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 protected active ingredient information to any person unless **subpart 3 of Part 4** allows it to be disclosed.

(5) 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.

(6) This section applies despite anything to the contrary in any contract, deed, or document.

(7) 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 professional body for health practitioners or veterinarians:

(k) the Serious Fraud Office:

(l) Worksafe New Zealand:

(m) the department responsible for the administration of a relevant law (as defined in **section 60**):

(n) an entity with regulatory functions under an Act that the regulations say is a regulatory entity.

344 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.

345 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 343** (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) This section does not permit protected active ingredient information to be disclosed unless **subpart 3 of Part 4** allows it to be disclosed.

(3) 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:

(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

Not complying with this section may be an offence (*see* **section 263**).

Subpart 4—Decision making and exercise of powers

346 Regulator may rely on decisions etc of recognised 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, a recognised entity.

(2) The Regulator may, by Regulator's notice, designate any of the following as a recognised entity:

(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.

347 Advisory committees

(1) The Regulator may establish 1 or more advisory committees to advise the Regulator in performing their functions and exercising their powers.

(2) The committee members must be persons who the Regulator is satisfied have knowledge, skills, and experience relevant to the matters on which the committee is to provide advice (including knowledge of mātauranga Māori when that is relevant).

(3) Committee members are appointed on the terms and conditions determined by the Regulator.

348 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 suitable 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.

349 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 211 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.

350 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 suitable 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.

351 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—

(a) the ability of the Regulator to perform the function or exercise the power; or

(b) the Regulator's 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.

352 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 for those market authorisations to be issued.

353 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 action may be completed or redone by the Regulator.

354 Opportunity to comment

(1) If the Regulator is required under this Act to give a person an **opportunity to comment** before a power is exercised, before exercising the power the Regulator must—

(a) notify the person of 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 any submissions made in that time into account.

(2) However, the Regulator need not comply with **subsection (1)** if—

(a) all of the persons who 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.

355 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 5** (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 a notice under **subsection (2)**).

(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.

356 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.

(5) The Regulator must not give protected active ingredient information to any person unless **subpart 3 of Part 4** allows it to be disclosed.

Subpart 5—Review of Regulator's decisions

357 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 337**.

Guidance note

Sections 355 and 374 set out requirements for giving notice of decisions and service of documents.

358 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 appropriate 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.

359 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.

360 Decision on review

(1) After reviewing the original decision, the review panel must—

(a) confirm the original decision; or

(b) set aside the original decision and refer the matter back to the Regulator for the Regulator to make a new decision.

(2) The review panel must notify the applicant and Regulator of its decision.

(3) If the matter is referred back to the Regulator, the Regulator must—

(a) reconsider the matter in accordance with any recommendations made by the review panel; and

(b) make a new decision.

361 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.

362 Other proceedings

(1) Applying for a review of a decision under this subpart does not affect any 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

363 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; 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 373**.

Subpart 2—Applications, notices, etc

Applications

364 Applications to Regulator

(1) This section and **sections 365 to 371** apply to an application to the Regulator for the purposes of this Act, other than an application for review under **section 357**.

(2) To make the application, 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 **section 337**.

(3) The application must include the information required by the rules.

365 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 they reasonably need to assess the application:

(b) allow the Regulator (or a person authorised by them) to inspect any place, equipment, process, document, or other thing that they reasonably need 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.

366 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**.

367 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 365**, 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.

368 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.

369 Regulator may reject non-complying application

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

(a) **section 364** is not complied with; or

(b) a request made under **section 365** is not complied within the specified time; or

(c) the Regulator is satisfied on reasonable grounds that any information in the application is misleading information.

370 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 it is an application for a standard authorisation for a medicine or medical device, to issue a provisional authorisation for the medicine or device.

371 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

372 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 **section 337**.

(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).

373 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, this section does not require the Regulator to publish information that could properly be withheld under the Official Information Act 1982 if a request for it were made under that Act.

(4) This section is subject to the Privacy Act 2020.

374 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 282** 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

375 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 377(3) or 378(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 380**.

376 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 it is an offence involving 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 277** 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 out—

(a) an infringement fee of not more than $1,000; and

(b) a fine of not more than $5,000.

377 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 applicable 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 **subsection (3)** may be made under **section 375(2)**.

Consultation requirements are set out in **section 380**.

378 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 applicable 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 381**).

Guidance note

Regulations setting criteria and requirements for **subsection (3)** may be made under **section 375(2)**.

Consultation requirements are set out in **section 380**.

Public availability requirements are set out in **section 373**.

379 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 380**.

380 Consultation

(1) The Regulator must comply with **subsection (3)** 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 **subsection (3)**.

(3) The Regulator must—

(a) consult the persons who the Regulator thinks—

(i) are likely to be substantially affected by the instrument; or

(ii) have knowledge, skills, and experience of any mātauranga Māori that is relevant to the instrument; and

(b) 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 professional body.

(5) However, the Regulator need not comply with **subsection (3)** 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.

(6) A failure to comply with this section does not affect the validity of the instrument.

(7) In this section, **instrument** means regulations, rules, a Regulator's notice, or an exemption under **section 379**.

381 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 378(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

382 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 373**.

Part 11
Repeals, revocations, and amendments to other enactments

Subpart 1—Repeals and revocations

383 Repeals 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).

384 Amendments to Food Act 2014

(1) This section amends the Food Act 2014.

(2) However, this section has no effect if **section 383** of this Act comes into force on or before 1 March 2026.

(3) In section 413(3)(b), replace "1 March 2026" with "**section 383** of the Therapeutic Products Act **2022** commences".

(4) In section 420(3)(b), replace "1 March 2026" with "**section 383** of the Therapeutic Products Act **2022** commences".

Guidance note

More amendments are made to the Food Act 2014 by **section 423** and **Schedule 4**.

385 Part repealed

This Part is repealed on the day after the day on which **section 67** comes into force.

Subpart 2—Amendments to Health Practitioners Competence Assurance Act 2003

386 Principal Act

This subpart amends the Health Practitioners Competence Assurance Act 2003.

387 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 **2022**

prescribe, in relation to a medicinal product, has the same meaning as in **section 53** of the Therapeutic Products Act **2022**

standing order has the same meaning as in **section 54** of the Therapeutic Products Act **2022**

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

After section 11(2), insert:

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

389 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)**.

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

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

391 New sections 14A and 14B inserted

After section 14, insert:

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

(1) This section applies in relation to a scope of practice that includes the prescribing of medicinal products.

(2) The responsible authority must not amend the prescribing provisions (as defined in **section 11A**) unless—

(a) the amendments comply with the requirements referred to in **section 11A(2)**; and

(b) the Minister has approved the amendments.

(3) The Minister may direct the responsible authority to amend the scope of practice to revoke or amend the prescribing provisions.

(4) Before giving a direction under **subsection (3)**, the Minister must give the responsible authority a reasonable opportunity to show why the scope of practice should not be changed (including allowing the authority a reasonable time to consult the persons referred to in section 14(2)(a) and (b)).

(5) If the Minister gives a direction under **subsection (3)**,—

(a) the responsible authority must comply with the direction within the time specified in it; and

(b) if the authority does not do so, the Minister may exercise the authority's 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 **subsection (5)**.

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 **2022**.

(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 **2022**).

(3) The power of the Minister to delegate under this section—

(a) is subject to any prohibitions, restrictions, or conditions contained in this or any other Act in relation to the delegation of the Minister's functions or powers; but

(b) does not limit any other power of delegation conferred on the Minister by this or any other Act.

392 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 **2022**.

393 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 **2022**; or

394 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:

395 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 2022

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, 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 69** of the Therapeutic Products Act **2022** 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 **2022** on and after the commencement date

old prescribing regime, for a profession, means the ability of health practitioners in that profession to prescribe medicines and issue standing orders under the Medicines Act 1981 immediately before the commencement date.

Subpart 3—Medicines Act 1981

396 Amendments to Medicines Act 1981

This subpart amends the Medicines Act 1981.

397 Long Title repealed

Repeal the Long Title.

398 Section 1 amended (Short Title and commencement)

In section 1(1), replace "Medicines" with "Pharmacy Ownership".

399 Section 2 amended (Interpretation)

(1) In section 2(1), delete all of the definitions except the definitions of **business**, **dispensing**, **health service**, **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 2022, have the same meanings in this Act as they have in that Act.

400 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**".

401 Section 5C repealed

Repeal section 5C.

402 Part 1 repealed

Repeal Part 1.

403 Part 2 heading repealed

Repeal the heading to Part 2.

404 Sections 17 to 42B and headings repealed

Repeal sections 17 to 42B and the headings above sections 24A, 24C, 25, 34A, 35, and 42A.

405 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".

406 Sections 43 to 49A and heading repealed

Repeal sections 43 to 49A and the heading above section 43.

407 Part 3 heading repealed

Repeal the heading to Part 3.

408 Sections 50 to 55C and heading repealed

Repeal sections 50 to 55C and the heading above section 55D.

409 Section 55D amended (Restriction on companies operating pharmacies)

In section 55D(1) and (2), replace "licence to operate a pharmacy" with "pharmacy licence".

410 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".

411 Part 4 repealed

Repeal Part 4.

412 Part 5 heading repealed

Repeal the heading to Part 5.

413 Sections 63 to 77 repealed

Repeal sections 63 to 77.

414 Sections 79 to 87 repealed

Repeal sections 79 to 87.

415 Parts 6 to 7A repealed

Repeal Parts 6 to 7A.

416 Part 8 heading repealed

Repeal the heading to Part 8.

417 Sections 97 to 104 repealed

Repeal sections 97 to 104.

418 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).

419 Sections 105A and 105B repealed

Repeal sections 105A and 105B.

420 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”.

421 Sections 105D to 115 repealed

Repeal sections 105D to 115.

422 Schedules 1AA to 3 repealed

Repeal Schedules 1AA to 3.

Subpart 4—Other legislation

423 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 referred 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 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 (*instead see* **clause 5** of this Schedule); or

(b) an NHP under this Act (*instead see* **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 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) is now a medical device under this Act (*instead see* **clause 5** of this Schedule); or

(b) is now an NHP under this Act (*instead see* **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 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 maybe 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) 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 under 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 referred 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 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 maybe 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 121(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 of **subparagraphs (i) or (ii)** apply, 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 maybe extended under **clause 19** of this Schedule.

11 Unlisted medical device or unregulated product and 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 121(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 of **subparagraphs (i) or (ii)** apply, 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 maybe 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 125(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 of **subparagraphs (i) or (ii)** apply, 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 (*instead see* **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 67** 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 clause.

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 358** of this Act; and

(b) the panel must review the matter and make a decision under **section 360** 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.

(2) If—

(a) a consent is given under **clause 13, 15, or 16**; or

(b) approval is given under **clause 17** of this Schedule,—

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 acting under a delegation from the EPA given under section 19 of that Act.

(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 135** 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 121(2) or 125(2)** of this Act.

21 What happens if market authorisation created by this Part but 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 thought there is no sponsor.

(3) The Regulator may exercise their power under **section 130** 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 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 an 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	Lapses—*see* **clause 24**
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
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 suncreen 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 that is lawfully being conducted at commencement if, on commencement, the clinical trial, and the persons (the **investigators**) conducting the trial, have been approved by the Director-General on the recommendation of the Health Research Council of New Zealand under section 30 of the 1981 Act.

(2) 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 that is lawfully being conducted at commencement if, on commencement, the clinical trial and the persons (the **investigators**) conducting the trial have not been approved by the Director-General on the recommendation of the Health Research Council of New Zealand under section 30 of the 1981 Act.

(2) 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

Exemptions under sections 25 and 29 of 1981 Act

31 6-month grace period for authorised prescribers and others

(1) This clause applies to a person who was 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

32 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 53** of this Act.

33 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 54(3)** of this Act.

Innovative medicine application protection periods

34 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 148** of this Act).

(2) In the definition of **innovative medicine application**, **paragraph (b)**, 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

35 Pending appeal from 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 358** of this Act; and

(b) the panel must review the matter and notify the Regulator of its decision under **section 360** 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

36 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 206** 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 220** of this Act that expires 12 months after commencement (or on any earlier date specified in the notice).

37 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 222** of this Act that expires 12 months after commencement (or on any earlier date specified in the notice).

38 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 220** 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 206** 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

Fees

39 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) The applicant must pay the transitional evaluation fee set out in the regulations.

(4) 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.

40 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 39** 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

41 Principles guiding exercise of powers includes 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.

42 New regulatory and investigative powers and administrative provisions apply to matters under this Part

(1) **Sections 198 to 201, subpart 2 of Part 7, subpart 1 of Part 8**, and **subparts 4 and 5 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 5 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

43 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) 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).

(4) The Minister must not recommend that regulations be made for 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.

(5) This clause is repealed, and any regulations made under it are revoked, 5 years after commencement.

Schedule 2
Crown-enforceable offences and Crown-enforceable infringement offences

ss 299 and 300

Provision contravened	Crown-enforceable offence	Crown-enforceable infringement offence
s 67 (Market authorisation required to import, supply, or export)	✓	✓
s 68 (Sponsor's consent required to import product with NZ authorisation)	✓	✓
s 69 (Controlled activity prohibited unless allowed by licence, permit, or **subpart 3**)	✓	✓
s 70 (Non-wholesale supply of prescription medicine: prescription required)	✓	
s 72 (Person in supply chain must comply with rules)	✓	✓
s 73 (Person in supply chain must comply with qualification, training, and competency requirements)	✓	✓
s 74 (Prohibited products)	✓	
s 139 (Sponsor must ensure compliance with market authorisation)	✓	✓
s 140 (Sponsor must ensure product meets product standards)	✓	✓
s 141 (Sponsor must ensure product meets export standards)	✓	✓
s 142 (Sponsor must have surveillance and response system)	✓	✓
s 143 (Sponsor must comply with rules)	✓	✓
s 144 (Sponsor must notify Regulator of certain minor changes)	✓	✓
s 145 (Sponsor of reportable product must notify Regulator of likely shortage)		✓
s 146 (Sponsor of reportable product must notify decision to stop supplying product)		✓
s 180 (Licensee or permit holder must ensure health practitioner or veterinarian has authority and resources)	✓	
s 181 (Licensee, permit holder, or senior manager must not induce health practitioner or veterinarian to act unprofessionally)	✓	
s 182 (Licensee and permit holder must comply with qualification, training, and competency requirements)	✓	
s 184 (Protection of responsible person from retaliation)	✓	
s 185 (Responsible person must comply with rules)		✓
s 186 (Pharmacy licensee must ensure pharmacy activities are carried on by persons allowed to do so)	✓	✓
s 187 (Tampering with therapeutic products)	✓	
s 188 (Supply chain activity with tampered-with products)	✓	

Provision contravened	Crown-enforceable offence	Crown-enforceable infringement offence
s 189 (Notifying Regulator of suspicion of tampering)	✓	✓
s 190 (Misrepresentation about therapeutic product)	✓	✓
s 196 (Agreeing or offering to carry on supply chain activity unlawfully)		✓
s 198 (Misleading information in records)	✓	✓
s 199 (Misleading information to Regulator or inspector)	✓	✓
s 200(1) (Compliance with regulatory or investigative requirement)	✓	✓
s 201 (Impeding Regulator or inspector)	✓	
s 215 (Compliance with recall order)	✓	
s 217 (Compliance with premises restriction order)	✓	
s 221 (Compliance with directions order)	✓	
s 223 (Compliance with product moratorium order)	✓	✓
s 225 (Compliance with prohibited product order)	✓	✓
s 228 (Compliance with medicine access limitation order)	✓	✓
s 294 (Compliance with enforceable undertaking)	✓	
s 345 (Information not to be disclosed)	✓	

Schedule 3
Reviewable decisions

s 357

Section	Description	Who may apply for review
	NHPs	
s 21(5)	Notice that NHP is a medicine	Applicant
s 62	Amendment of rules setting out standard health benefit claims	Applicant
	Market authorisations	
s 118	Application and issue of market authorisation for medicine or medical device	Applicant
s 123	Issue of market authorisation for NHP	Applicant
s 130	Change of sponsor	Sponsor
s 133	Conditions on market authorisation	Applicant or sponsor
s 134	Variation of market authorisation on application by sponsor	Sponsor
s 135	Variation of market authorisation by Regulator	Sponsor
s 137	Regulator may cancel market authorisation if grounds exist	Sponsor
s 138	Regulator may cancel market authorisation on application	Sponsor
	Licences and permits	
s 156	Grant of licence	Applicant
s 164	Grant of permit	Applicant
s 167	Conditions on licence or permit	Licensee or permit holder
s 168	Variation of licence or permit	Licensee or permit holder
s 171	Regulator may suspend or cancel if grounds exist	Licensee or permit holder
s 173	Regulator may suspend or cancel on application	Licensee or permit holder
s 175	Lifting of suspension	Licensee or permit holder
	Regulatory powers	
s 234	Variation of regulatory order	Applicant
s 235	Revocation of regulatory order	Applicant
s 237	Official statement for export of therapeutic product	Applicant

Schedule 4
Amendments to other Acts

s 423

Accident Compensation Act 2001

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 **2022**); or

Replace clause 3(1)(c) of Schedule 1 with:

(c) pharmaceuticals supplied, prescribed, or administered by a treatment provider who is allowed to do so under the Therapeutic Products Act **2022**:

Agricultural Compounds and Veterinary Medicines Act 1997

In section 4A(5), replace "Medicines Act 1981" with "Therapeutic Products Act **2022**".

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 **2022**), 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 **2022**:

Animal Products Act 1999

Replace section 161(5)(a)(vii) with:

(vii) the Therapeutic Products Act **2022**:

Animal Welfare Act 1999

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 **2022**; 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

Replace section 117A(2)(g) with:

(g) the Therapeutic Products Act **2022**:

Contraception, Sterilisation, and Abortion Act 1977

Repeal section 6.

Contract and Commercial Law Act 2017

In Schedule 5, Part 2, repeal the item relating to the Medicines Regulations 1984.

Copyright Act 1994

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 **2022**; 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 **2022**; and

Coroners Act 2006

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 **2022**)

Corrections Act 2004

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 **2022**)

In section 3(1), replace the definition of **medicine** with:

> **medicine** has the same meaning as in **section 22** of the Therapeutic Products Act **2022**

Costs in Criminal Cases Act 1967

In section 4(5), replace "or the Resource Management Act 1991" with "the Resource Management Act 1991, or the Therapeutic Products Act **2022**".

In section 7(3), replace "or the Resource Management Act 1991" with "the Resource Management Act 1991, or the Therapeutic Products Act **2022**".

In section 10(2), replace "or the Resource Management Act 1991" with "the Resource Management Act 1991, or the Therapeutic Products Act **2022**".

Crown Organisations (Criminal Liability) Act 2002

After section 6(1)(e), insert:

> (f) a Crown-enforceable offence as defined in **section 299** of the Therapeutic Products Act **2022**

Crown Organisations (Criminal Liability) Act 2002—*continued*

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 **2022**; and

After section 10(b)(vii), insert:

(viii) **section 206 or 240** of the Therapeutic Products Act **2022**; or

Customs and Excise Act 2018

Repeal section 242(1)(b)(v).

After section 242(1)(b)(vi), insert:

(vii) the Therapeutic Products Act **2022**:

In section 302(4), definition of **Ministry-related border management function**, after paragraph (c)(v), insert:

(va) the Therapeutic Products Act **2022**:

Fair Trading Act 1986

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 **2022**), except in relation to its price.

Food Act 2014

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—*continued*

therapeutic product has the meaning given by **section 16** of the Therapeutic Products Act **2022**

Replace section 368(3)(d) with:

(d) the Therapeutic Products Act **2022**

Hazardous Substances and New Organisms Act 1996

In section 2(1), definition of **innovative medicine application**, replace "section 23A of the Medicines Act 1981" with "**section 148** of the Therapeutic Products Act **2022**".

In section 2(1), repeal the definition of **qualifying medicine**.

In section 2(1), definition of **qualifying organism**, replace "medicine" with "therapeutic product".

In section 2(1), definition of **responsible chief executive**,—

(a) after "Authority and", insert "the Regulator under the Therapeutic Product Act **2022** or":

(b) delete "Medicines Act 1981 or the".

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 **2022**

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 "medicines" with "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".

In section 38I(4), replace "medicine" with "therapeutic product" in each place.

Replace section 38I(5)(a) with:

Hazardous Substances and New Organisms Act 1996—*continued*

(a) for any person to carry on an activity that is regulated under the Therapeutic Products Act **2022** 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 "medicine" with "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 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 **2022**

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 **2022** 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 each place.

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".

In section 49I(1), replace "medicine" with "therapeutic product" in each place.

In section 49L(2), replace "medicine" with "therapeutic product" in each place.

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 **2022** applies (with the

Hazardous Substances and New Organisms Act 1996—*continued*

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

In section 6, repeal the definition of **medicine**.

In section 6, insert in its appropriate alphabetical order:

> **manufacture**, in relation to a therapeutic product, has the same meaning as in **section 41** of the Therapeutic Products Act **2022**
>
> **therapeutic product** has the same meaning as in **section 16** of the Therapeutic Products Act **2022**
>
> **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 **2022**; or
>
> (ii) it is used in the manufacture of a therapeutic product that is lawfully carried on under the Therapeutic Products Act **2022**; 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**,—

(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".

Human Tissue Act 2008—*continued*

In section 61(3)(d), replace "or a 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 **2022** in addition to any restrictions under this section.

Land Transport Act 1998

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 **2022**); but

Maritime Transport Act 1994

In section 20(1), replace "Medicines Act 1981" with "Therapeutic Products Act **2022**".

In section 50(1)(e), replace "Medicines Act 1981" with "Therapeutic Products Act **2022**".

In section 52(1)(b)(i)(A) and (ii), replace "Medicines Act 1981" with "Therapeutic Products Act **2022**".

Misuse of Drugs Act 1975

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 **2022**)

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 **2022**) for that drug, other than a medical practitioner, dentist, nurse practitioner, optometrist, or midwife
>
> **prescription** means a complying prescription (as defined in **section 53** of the Therapeutic Products Act **2022**)
>
> **standing order** means a complying standing order (as defined in **section 54** of the Therapeutic Products Act **2022**)

In section 13(4), replace the definition of "**pharmacy employee**" with:

> **pharmacy employee** means a pharmacy worker as defined in **section 52** of the Therapeutic Products Act **2022**.

Ombudsmen Act 1975

In Part 2 of Schedule 1, delete the items for Medicines Classification Committee and Medicines Review Committee.

Pae Ora (Healthy Futures) Act 2022

In section 4, replace the definition of **pharmaceutical** with:

> **pharmaceutical** means a medicine, medical device, or NHP (as defined in **sections 22, 24 and 29** of the Therapeutic Products Act **2022**) 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 **2022**) or related product or related thing

Psychoactive Substances Act 2013

Replace section 9(3)(c), (d), and (e) with:

> (c) a therapeutic product (as defined in **section 16** of the Therapeutic Products Act **2022**)

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 **2022**; and

Repeal section 16(3)(c).

Public Safety (Public Protection Orders) Act 2014

In section 3, definition of **prohibited item**, paragraph (b), replace "section 3 of the Medicines Act 1981" with "**section 22** of the Therapeutic Products Act **2022**".

In section 3, definition of **prohibited item**, paragraph (c), replace "Medicines Act 1981" with "Therapeutic Products Act **2022**".

section 92A, definition of **drug or alcohol requirement**, paragraph (a), replace "Medicines Act 1981" with "Therapeutic Products Act **2022**".

Search and Surveillance Act 2012

In the Schedule, insert in its appropriate alphabetical order:

Therapeutic Products Act **2022**	**s 209**	Inspector may enter a home, marae or related building, or treatment or consulting room to exercise powers of inspection	Subpart 3
	s 212	Imported consignments may be detained by Customs pending testing	section 159

Search and Surveillance Act 2012—*continued*

s 240	Inspector may enter and search a place to investigate and enforce compliance with Act, including obtaining evidential material	All (except sections 118 and 119)
s 241	Inspector may obtain search warrant for purposes of **s 240**	Subpart 3
s 244	Regulator may destroy certain things seized by the Regulator, an inspector, or Customs	section 160

Sentencing Act 2002

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 **2022**".

Smokefree Environments and Regulated Products Act 1990

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)" with "that has a market authorisation under the Therapeutic Products Act **2022** 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 **2022**".

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 NZ authorisation under the Therapeutic Products Act **2022**".

Substance Addiction (Compulsory Assessment and Treatment) Act 2017

In section 4, definition of **drug**, replace paragraph (b) with:

(b) a prescription medicine or pharmacist medicine (as defined in **section 14** of the Therapeutic Products Act **2022**)

Summary Proceedings Act 1957

In section 2(1), definition of **infringement notice**,—

(a) insert the following as the second to last paragraph—

(jk) **section 279** of the Therapeutic Products Act **2022**; or

(b) make any necessary consequential amendment to the numbering of that paragraph.

Trade Marks Act 2002

Replace section 98(2) with:

Trade Marks Act 2002—*continued*

(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 **2022**.

Veterinarians Act 2005

In section 50(1)(a)(C) replace "Medicines Act 1981" with "Therapeutic Products Act **2022**".

Repeal section 89A(a)(vii).

After section 89A(a)(viii), insert:

(ix) the Therapeutic Products Act **2022**; or

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