The main problem for industrial hemp is highlighted in page 4 of the “Explantory Note”

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.

Extracts from the Act

1 Title

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

Commencement 1 September 2026

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.

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.

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.

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.

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)**.

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(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.

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.

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.

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.

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**.

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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.

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:

(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.

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**).

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**.
