Natural Health Products Bill

Government Bill

Explanatory note

General policy statement

The Natural Health Products Bill establishes a system for the regulation of low-risk natural health products in New Zealand.

Natural health products include herbal remedies, traditional treatments, homeopathic remedies, and dietary supplements. The system will, for the first time in New Zealand, introduce risk-based regulation of natural health products. It will use an approach that enables product sponsors to gain market authorisation by self-certification against the system requirements.

The Bill provides for—

- the establishment of a natural health products regulator within the Ministry of Health:
- natural health products to be notified to an online register:
- recognition of assessments by approved regulators of ingredients, claims and evidence of health benefits, and manufacturing standards:
- a list of prohibited ingredients:
- notification of new ingredients prior to marketing:
- export certification:
- an appeals mechanism:

- regulation-making powers to set labelling requirements, manufacturing standards, and standards of evidence required to make a claim of health benefit:
- an exemption from notification and manufacturing requirements for certain categories of product, including those made by a practitioner for a patient:
- the appointment of a technical expert advisory committee.

Regulatory impact statement

The Ministry of Health produced a regulatory impact statement in December 2010 to help inform the main policy decisions taken by the Government relating to the contents of this Bill.

A copy of this regulatory impact statement can be found at—

- http://www.health.govt.nz/about-ministry/legislation-and-regulation/regulatory-impact-statements/development-natural-health-pr
- http://www.treasury.govt.nz/publications/informationreleases/ris

Clause by clause analysis

Clause 1 is the title clause.

Clause 2 provides for commencement of the Act to occur on a date fixed by the Governor-General by Order in Council. One or more orders may be made bringing different provisions of the Act into force at different times. This will allow time for the development of the natural health product database and for regulations that give effect to some parts of the Act to be made.

Part 1
Preliminary matters

Preliminary provisions

Clause 3 states that the purpose of the Act is to establish a system for the regulation of natural health products in New Zealand.

Clause 4 states the principles on which the Act is based.

Clause 5 provides for the interpretation of terms used in the Act.

Clause 6 defines **natural health product**. The key aspects of the definition relate to what the product contains, how it is to be administered, and the intended health benefit of the product.

Clause 7 provides that the Act binds the Crown.

Natural Health Products Regulatory Authority

Clause 8 establishes the Natural Health Products Regulatory Authority (the **Authority**), who is to be the Director-General of Health.

Clause 9 allows for the recognition of other regulatory authorities, whether in New Zealand or in any other country.

Natural health products advisory committee

Clause 10 requires the Authority to establish an advisory committee to provide expert advice to the Authority. The maximum number of committee members is 8. Each member must have expertise in an area of knowledge that relates to or is relevant to natural health products.

Natural health product database

Clause 11 requires the Authority to establish and maintain a natural health product database.

Sponsor

Clause 12 requires that the sponsor of a natural health product must be resident in New Zealand.

Part 2
Regulation of natural health products

Product notification of natural health products

Clause 13 requires the sponsor of any natural health product to be distributed in New Zealand to complete a product notification for the product. Product notification is to be made to the Authority and requires the sponsor to provide information about the product, the sponsor, the manufacturer, the health benefit claims made for the product, and any other prescribed information. Product notification is not required in respect of certain natural health products made by a prac-

titioner for the treatment of a patient, any export-only natural health products, or any exempted natural health products.

Clause 14 allows the Authority to exempt, by notice in the *Gazette*, a natural health product or category of natural health product from the requirement to have a product notification.

Clause 15 allows the Authority to audit any product notification or class of product notification.

Clause 16 requires the Authority to suspend the product notification of any natural health product that the Authority has reasonable grounds to believe has caused, is causing, or is likely to cause harm to any person. The Authority may suspend a product notification if—

- it has reasonable grounds to believe that the sponsor has given false, misleading, or incomplete information in the product notification; or
- it has reasonable grounds for concern because of new information about the safety, quality, health benefit claims, or manufacturing standards of the natural health product.

The Authority may cancel the product notification if satisfied that the events leading to the suspension have occurred or that any concern leading to the suspension is justified. The effect of any suspension or cancellation is that the sponsor must stop distributing the product.

Clause 17 requires the sponsor of a notified natural health product to notify the Authority as soon as the sponsor becomes aware of any serious adverse reaction to the product.

Clause 18 sets out the situations when a new product notification is required for a natural health product.

Clause 19 enables the sponsor of a natural health product to cancel the product notification of the product if the product is no longer sold or supplied.

Ingredients of natural health products

Clause 20 empowers the Authority to declare any substance that belongs to any class of substance in the *Schedule* to be a natural health product ingredient. *Clause 20(3)* allows the Authority to conduct a safety assessment of the substance and sets out the criteria that the Authority must consider in its decision.

Clause 21 empowers the Authority to declare a substance to be a prohibited natural health product ingredient and sets out the criteria to be applied.

Every declaration of a natural health product ingredient or prohibited ingredient must be published on an Internet site maintained by or on behalf of the Authority. After making a declaration, the Authority must—

- arrange for publication in the *Gazette* of a notice indicating that the declaration has been made; and
- list the natural health product ingredient or prohibited ingredient on the natural health product database.

New ingredients

Clause 22 regulates the use of new ingredients in a natural health product. A new ingredient means any substance that belongs to a class of substance listed in the *Schedule* and that is not—

- a natural health product ingredient; or
- a prohibited ingredient.

Clause 23 provides for safety assessments of new ingredients.

Labelling

Clause 24 requires natural health products that are distributed in New Zealand to comply with the labelling requirements prescribed in regulations.

Exports

Clause 25 allows the sponsor of a natural health product to apply to the Authority for an export certificate. If the natural health product is manufactured in New Zealand but is not to be distributed in New Zealand, the sponsor must also hold a licence to manufacture.

Clause 26 provides that if a natural health product is also an animal product within the meaning of the Animal Products Act 1999, any application for an export certificate or a similar statement for that product must be made according to that Act instead of this Act.

Code of practice for manufacture of natural health products

Clause 27 requires the Authority to establish a code of practice for the manufacture of natural health products (the **code**).

Manufacture of natural health products

Clauses 28 to 34 relate to the manufacture of natural health products. A person, other than an exempted person, must not manufacture a natural health product without a licence to manufacture granted by the Authority.

The Authority may grant a licence to manufacture if satisfied that—

- the applicant's manufacturing facilities meet the requirements of the code; and
- the applicant is a fit and proper person to hold the licence.

It is a condition of a licence to manufacture that the licence holder must at all times comply with the code, and the Authority may, at any time, audit manufacturing facilities for compliance with the code or any condition imposed by the Authority.

Fees

Clause 35 authorises the Authority to prescribe, by notice in the *Gazette*, fees payable under this Act.

Sanctions and penalties

Clauses 36 to 40 prescribe offences in respect of the following:

- deceptive conduct:
- sale of natural health products that have not been notified or do not meet required standards:
- manufacturing a natural health product without a licence:
- obstruction of authorised persons:
- endangerment of human health.

Disputes

Clause 41 establishes the Natural Health Product Appeals Committee to determine appeals made to it against decisions of the Authority.

Clause 42 relates to the making of appeals and allows a further appeal on a question of law to be made to the High Court.

Other powers of Authority

Clause 43 enables the Authority to publish statements relating to natural health products.

Clause 44 provides for the recall of natural health products.

Clause 45 enables delegations to be made by the Authority of its powers, functions, or duties under this Act.

Transitional provisions

Clause 46 provides transitional arrangements for products that were sold before the commencement of this Act and that—

- comply with *paragraphs (a), (c), and (d)* of the definition of natural health product in *clause 6(1)*; and
- do not contain (as ingredients) any substance that does not belong to a class of substance listed in the *Schedule*.

Regulations

Clause 47 empowers the making of regulations on the recommendation of the Minister of Health after complying with certain consultation requirements.

Review of Act

Clause 48 requires the Ministry of Health to conduct a review of the policy of the Act no later than 5 years after the commencement of the Act.

Amendments to enactments

Clauses 49 to 56 make consequential amendments to the Medicines Act 1981 and to the Misuse of Drugs Amendment Act 2005.

Revocation

Clause 57 revokes the Dietary Supplements Regulations 1985.

Hon Dr Jonathan Coleman

Natural Health Products Bill

Government Bill

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Schedule 29
Suitable classes of substances

The Parliament of New Zealand enacts as follows:

1 Title

This Act is the Natural Health Products Act **2011**.

2 Commencement

This Act comes into force on a date appointed by the Governor-General by Order in Council and 1 or more orders may be made bringing different provisions into force on different dates.

Part 1
Preliminary matters

Preliminary provisions

3 Purpose

The purpose of this Act is to establish a system for the regulation of natural health products in New Zealand.

4 Principles

This Act is based on the following principles:

(a) that natural health products must be fit for human consumption or use:

(b) that the regulation of natural health products must be proportionate to the risks associated with their use:

(c) that natural health products must be accompanied by information that is accurate and tells consumers about the risks and benefits of using the product.

5 Interpretation

In this Act, unless the context otherwise requires,—

appeals committee means the Natural Health Product Appeals Committee established under **section 42**

authorised person means any person to whom the Authority has delegated any powers, functions, or duties under **section 45**

Authority means the Natural Health Products Regulatory Authority established under **section 8**

code means the code of practice for manufacturing natural health products established under **section 27**

food means anything that is used or represented for use as food or drink for human beings; and includes—

(a) any ingredient or nutrient or other constituent of any food or drink, whether that ingredient or nutrient or other constituent is consumed or represented for consumption by human beings by itself or when used in the preparation of or mixed with or added to any food or drink; and

(b) anything that is or is intended to be mixed with or added to any food or drink; and

(c) chewing gum, and any ingredient of chewing gum, and anything that is or is intended to be mixed with or added to chewing gum

health benefit means any 1 of the following benefits:

(a) the maintenance or promotion of health or wellness:

(b) nutritional support:

(c) vitamin or mineral supplementation:

(d) affecting or maintaining the structure or function of the body:

(e) relief of symptoms of any condition that is not a serious condition

health benefit claim means a claim of a health benefit

licence to manufacture means a licence to manufacture natural health products granted under **section 29**

Minister means the Minister who, under the authority of any warrant or with the authority of the Prime Minister, is for the time being responsible for the administration of this Act

natural health product has the meaning given to it in **section 6**

natural health product database means the database established under **section 11**

natural health product ingredient means any substance that—

(a) belongs to a class of substance that is listed in the **Schedule**; and

(b) is declared by the Authority to be a natural health product ingredient under **section 20**

notified natural health product means a natural health product for which a product notification has been completed

prescribed manner means the manner prescribed in regulations

product notification means the product notification required under **section 13**

prohibited ingredient means any ingredient declared by the Authority to be a prohibited ingredient under **section 21**

recognised authority means a person or body declared to be a recognised authority under **section 9**

regulations means regulations made under this Act

serious condition means a disease, disorder, condition, ailment, or defect (or any symptom of the disease, disorder, condition, ailment, or defect) that is generally accepted as not suitable for at least 1 of the following:

(a) self-diagnosis:

(b) self-management

sponsor means, in relation to a natural health product, a person who imports or manufactures, or arranges the import or manufacture of, a natural health product.

6 Definition of natural health product

(1) In this Act, unless the context otherwise requires, a **natural health product** means a product—

(a) that is intended by the sponsor of the product—

(i) to be administered to a human being; and

(ii) to bring about a health benefit to the person to whom the product is administered; and

(iii) to be administered by any of the methods specified in **subsection (2)**; and

(iv) not to be administered by any of the methods specified in **subsection (3)**; and

(b) that, subject to **section 22(2)(b)(i)**, contains only natural health product ingredients; and

(c) that does not contain any prohibited ingredient; and

(d) that is not—

(i) a food; or

(ii) a prescription medicine or pharmacy-only medicine as those terms are defined in the Medicines Act 1981; or

(iii) a controlled drug within the meaning of the Misuse of Drugs Act 1975.

(2) The methods of administration referred to in **subsection (1)(a)(iii)** are the following:

(a) oral ingestion:

(b) application to the skin, scalp, or nails:

(c) application to the teeth, throat, anal canal, or vagina:

(d) application to the mucosa of the mouth or nose.

(3) The methods of administration referred to in **subsection (1)(a)(iv)** are the following:

(a) injection or parenteral infusion:

(b) application to the eye:

(c) application in the ear.

7 Act binds the Crown

This Act binds the Crown.

Natural Health Products Regulatory Authority

8 Natural Health Products Regulatory Authority

(1) This section establishes the Natural Health Products Regulatory Authority.

(2) The Authority is the Director-General of Health.

(3) The office of the Authority must be administered by the Ministry of Health.

9 Authority may declare recognised authorities

(1) The Authority may, by notice in the *Gazette*, declare a person or body to be a recognised authority—

(a) for the purpose of this Act, or for a specified purpose under this Act or provision of this Act; and

(b) for a specified period or not.

(2) Before declaring a person or body to be a recognised authority for the purpose of this Act, the Authority must be satisfied that the person or body (whether in New Zealand or any other country) administers a system for the regulation of natural health products that is equivalent to or more robust than the system administered under this Act.

(3) Before declaring a person or body to be a recognised authority for a specified purpose under this Act or provision of this Act, the Authority must be satisfied that the person or body (whether in New Zealand or any other country)—

(a) makes decisions in respect of natural health products that require the person or body to assess conformity against, or compliance with, standards that are equivalent to or more robust than those under this Act; or

(b) is engaged in an area of work that requires the person or body to assess conformity against, or compliance with, standards that are equivalent to or more robust than those under this Act.

Natural health products advisory committee

10 Natural health products advisory committee

(1) The Authority must establish an advisory committee to provide expert advice to the Authority on matters referred to it by the Authority.

(2) The committee must consist of not more than 8 members.

(3) The members of the committee must be appointed by the Authority on any terms and conditions that the Authority thinks fit.

(4) In appointing members of the committee, the Authority must ensure that each member has expertise in at least 1 area of knowledge that relates to or is relevant to natural health products.

(5) The Authority may give terms of reference—

(a) on the advice that the committee provides to the Authority; and

(b) on the use of external experts to assist the committee.

(6) The committee may, subject to any provision in this Act, the regulations, and the terms of reference, determine its own procedure.

Natural health product database

11 Natural health product database

The Authority must establish and maintain a natural health product database.

Sponsor

12 Sponsor must be resident in New Zealand

A sponsor of a natural health product must be resident in New Zealand within the meaning of section YD 1 or YD 2 (excluding section YD 2(2)) of the Income Tax Act 2007.

Part 2
Regulation of natural health products

Product notification of natural health products

13 Product notification of natural health products required before distribution

(1) A natural health product must not be distributed in New Zealand without a product notification having been completed for the product.

(2) The product notification must be made to the Authority and must be completed by the sponsor in the prescribed manner.

(3) The product notification is complete when—

(a) the sponsor has provided—

(i) information as required by regulations relating to the name of the product, the product details, the sponsor, the manufacturer, and the health benefit claims made for the product; and

(ii) any other information required by regulations; and

(b) the sponsor has provided a declaration that—

(i) the information provided is complete and accurate; and

(ii) the sponsor holds evidence to support the health benefit claims made for the product.

(4) The sponsor must, if requested by the Authority, provide the Authority with the evidence described in **subsection (3)(b)(ii)**.

(5) If a manufacturer of a natural health product is not in New Zealand and is not listed on the natural health product database, the sponsor of the product must satisfy the Authority that the manufacturer complies with the code after providing any documentation or information required by the Authority.

(6) This section does not apply to—

(a) any natural health product that is made by a practitioner to be administered to a particular person after being requested by or on behalf of that person to use the practitioner's own judgement as to the treatment required; or

(b) any export-only natural health product, unless it is a natural health product for which export certification is sought under **section 25**; or

(c) natural health products or categories of natural health products that are exempted under **section 14** from the requirements of this section.

(7) A sponsor is not required to complete a further product notification for a natural health product if there is any variation in the weight, size, or packaging (excluding the labelling) of the product.

(8) In this section, **evidence** means either of the following types of evidence, each of which must be consistent with any prescribed standard:

(a) scientific evidence:

(b) evidence based on traditional use of a substance or product.

14 Authority may exempt natural health products from product notification

The Authority may, by notice in the *Gazette*, exempt a natural health product or category of natural health product from the requirement to have a product notification under **section 13**.

15 Authority may audit notifications

(1) The Authority may at any time audit any product notification or class of product notification.

(2) The audit may be conducted in any manner that the Authority considers appropriate and consistent with the principles of this Act.

16 Authority may suspend or cancel product notifications

(1) The Authority must, as soon as practicable, suspend the product notification of any natural health product that the Authority has reasonable grounds to believe has caused, is causing, or is likely to cause harm to any person.

(2) The Authority may suspend a product notification if—

(a) the Authority has reasonable grounds to believe that the sponsor of the product has provided false, misleading, or incomplete information in the product notification; or

(b) the Authority has reasonable grounds for concern because of new information about the safety, quality, health benefit claims, or manufacturing standards of the natural health product.

(3) The Authority may—

(a) reinstate any product notification that has been suspended under **subsection (1)** if it is satisfied that there are no reasonable grounds to believe that the product has caused, is causing, or is likely to cause, harm to any person; or

(b) reinstate any product notification that has been suspended under **subsection (2)(a)** if it is satisfied that the sponsor did not provide false, misleading, or incomplete information; or

(c) reinstate any product notification that has been suspended under **subsection (2)(b)** if the concern referred to in that subsection is not justified.

(4) The Authority may cancel a product notification of any product if it is satisfied that any of the events described in **subsection (1)** or **(2)(a)** have occurred, or that any concern referred to in **subsection (2)(b)** is justified.

(5) The Authority must, as soon as practicable, give written notice to the sponsor of any suspension, cancellation, or reinstatement of the product notification.

(6) If a product notification for a natural health product is suspended or cancelled under this section, the sponsor of the product—

(a) must stop distributing the product on and from the date and time that the suspension or cancellation takes effect; and

(b) must not complete another product notification for the product.

17 Sponsor must notify Authority of any serious adverse reactions to natural health product

(1) The sponsor of a notified natural health product must notify the Authority as soon as the sponsor becomes aware of any serious adverse reaction to the product.

(2) In this section, **serious adverse reaction** means any reaction causing death, danger to life, hospitalisation, prolongation of hospitalisation, interruption of productive activity, or birth defects.

18 When new product notification needed

(1) If, in relation to a notified natural health product, there is any change in the product's manufacturing arrangements, health benefit claims, or ingredients, the sponsor of the product must—

(a) withdraw the product notification for the product; and

(b) complete a new product notification for the product that more accurately reflects the change.

(2) The sponsor may change the sponsor's contact details on a product notification without the need for a new product notification.

19 Sponsor may cancel product notification

A sponsor of a notified natural health product may cancel the product notification of the product if the product is no longer sold or supplied.

Ingredients of natural health products

20 Authority may declare substances to be natural health product ingredients

(1) The Authority may, for the purpose of this Act, declare any substance that belongs to any class of substance listed in the **Schedule** to be a natural health product ingredient.

(2) The Authority may impose restrictions on the use of any substance it has declared to be a natural health product ingredient.

(3) In considering whether a substance should be declared a natural health product ingredient, the Authority—

(a) may, if it raises a concern, conduct a safety assessment of the substance; and

(b) must have regard and give weight to, as it considers appropriate, the following:

(i) whether a recognised authority permits the use of the substance in a natural health product and, if so, whether it imposes any restrictions on the use of the substance:

(ii) whether the substance is recognised in traditional medicine or pharmacopoeias:

(iii) any other matter that the Authority considers relevant in the circumstances.

(4) Every substance declared to be a natural health product ingredient must be listed on the natural health product database along with any restrictions on the use of the substance.

(5) A declaration made under this section must be published on an Internet site maintained by or on behalf of the Authority.

(6) The Authority must, as soon as practicable after making any declaration under this section, arrange for publication in the *Gazette* of a notice indicating that the declaration has been made and include in the notice details of the Internet site on which the declaration is published.

21 Prohibited ingredients

(1) The Authority may, for the purpose of this Act, declare a substance to be a prohibited natural health product ingredient.

(2) In considering whether to declare the substance to be a prohibited natural health product ingredient, the Authority—

(a) must consider the risk of any harm arising from the use of the substance; and

(b) must have regard and give weight to, as it considers appropriate, the following:

(i) any history of human therapeutic use of the substance:

(ii) whether a recognised authority prohibits or restricts use of the substance for administration to human beings:

(iii) any other matter that the Authority considers relevant in the circumstances.

(3) Every substance declared to be a prohibited natural health product ingredient must be listed on the natural health product database.

(4) A declaration made under this section must be published on an Internet site maintained by or on behalf of the Authority.

(5) The Authority must, as soon as practicable after making any declaration under this section, arrange for publication in the *Gazette* of a notice indicating that the declaration has been made and include in the notice details of the Internet site on which the declaration is published.

New ingredients

22 If new ingredient intended for use in natural health product

(1) In this section and **section 23**, **new ingredient** means any substance that belongs to a class of substance listed in the **Schedule** and that is not—

(a) a natural health product ingredient; or

(b) a prohibited ingredient.

(2) If a manufacturer or distributor intends to use a new ingredient in a natural health product that is intended for distribution in New Zealand,—

(a) the manufacturer or distributor must notify the Authority in the prescribed manner and no later than 90 working days before the sponsor intends to complete a product notification for the product; and

(b) if, within the 90 working days, the Authority does not raise any concern or commence a safety assessment for the product,—

(i) the new ingredient may be used in the product; and

(ii) the sponsor may, after receiving notice from the Authority under this paragraph, complete a product notification for the product; and

(c) if, within the 90 working days, the Authority raises a concern and commences a safety assessment, the product must not be notified under **section 13**, sold, or distributed until or unless the Authority determines that the new ingredient may be used in the product.

(3) The Authority must, when determining whether the new ingredient may be used in the product, apply the criteria set out in **section 20(3)(b)(i) to (iii)**.

(4) If the Authority determines that the new ingredient may be used in the natural health product, the Authority must, as soon as practicable,—

(a) declare the new ingredient to be a natural health product ingredient in accordance with **section 20**; and

(b) list the new ingredient on the natural health product database in accordance with **section 20(4)**; and

(c) comply with **section 20(6)**.

23 Safety assessment of new ingredient

(1) If the Authority is notified of a new ingredient under **section 22**—

(a) the Authority must, as soon as practicable, notify the applicant as to whether a safety assessment will be undertaken; and

(b) if a safety assessment is to be undertaken, the Authority must, within 30 working days of being notified of the new ingredient, notify the applicant of—

(i) the outcome of the assessment; or

(ii) whether further time is needed to complete the assessment.

(2) The Authority may request further evidence of the safety of the new ingredient from the applicant.

Labelling

24 Labelling

A natural health product that is distributed in New Zealand must comply with the labelling requirements prescribed in regulations.

Exports

25 Export certificate

(1) A sponsor may, subject to **section 26**, apply to the Authority for an export certificate for a natural health product.

(2) Any application under this section must be accompanied by the prescribed fee (if any) and the sponsor must comply with any requests for information made by the Authority for the purposes of the application.

(3) The Authority may grant an export certificate for a natural health product if the sponsor has completed a product notification for the product.

(4) If the sponsor is seeking an export certificate for a natural health product that is manufactured in New Zealand but not distributed in New Zealand, the sponsor must, in addition to completing a product notification for the product, hold a licence to manufacture.

(5) The Authority may determine the form and content of the export certificate.

(6) An export certificate is not a guarantee that the natural health product—

(a) necessarily meets the commercial requirements of the consumer; or

(b) necessarily meets the specific requirements of overseas markets.

26 Natural health products that are animal products

Despite **section 25**, if a natural health product is also an animal product within the meaning of the Animal Products Act 1999, any application for an export certificate or a similar statement for that product must be made in accordance with that Act instead of this Act.

Code of practice for manufacture of natural health products

27 Code of practice for manufacture of natural health products

(1) The Authority must establish a code of practice for the manufacture of natural health products.

(2) In developing the code and any amendments to the code, the Authority must—

(a) comply with any requirements relating to the content of the code that is prescribed in regulations:

(b) consult with any person or organisation that the Authority considers is likely to be affected by the code or the proposed amendments to it.

(3) The Authority must ensure that the code, and every amendment to it,—

(a) specifies the date on which it takes effect:

(b) is published on an Internet site that is publicly available at all reasonable times:

(c) is available for purchase in hard copy, at a reasonable cost, from the Authority.

Manufacture of natural health products

28 Licence to manufacture natural health products

(1) A person must not manufacture a natural health product without a licence to manufacture granted under **section 29**.

(2) The following persons are exempt from **subsection (1)**:

(a) any exporter of a natural health product who is not also seeking an export certificate for the product; and

(b) any health practitioner who makes a natural health product to be administered to a particular person after being requested by or on behalf of that person to use the practitioner's own judgement as to the treatment required.

29 Application for licence to manufacture

(1) An application for a licence to manufacture natural health products must be made to the Authority in the prescribed manner.

(2) The Authority may grant a person a licence to manufacture natural health products if—

(a) the Authority has conducted an audit of the manufacturing facilities and is satisfied that the facilities meet the requirements of the code; and

(b) the Authority is satisfied that the person is a fit and proper person to hold the licence.

(3) In determining whether a person is a fit and proper person to manufacture natural health products, the Authority must take into account the following:

(a) any conviction of the person or any director or manager of the person for—

(i) any offence involving or relating to the manufacture of any product for human consumption; or

(ii) any offence specified in the regulations:

(b) whether there has in the past been a serious or repeated failure by the person to comply with any requirement under this Act:

(c) whether there are other grounds for considering that the person is likely in the future to fail to comply with those duties:

(d) any other matters that the Authority considers relevant.

(4) A licence to manufacture remains in force for 3 years after the date that it is granted, unless—

(a) the Authority specifies a shorter period for the licence; or

(b) it is earlier revoked.

30 Conditions of licence

(1) It is a condition of a licence to manufacture that the licence holder must at all times comply with the code.

(2) The Authority may, when granting a licence to manufacture, impose conditions on the licence as the Authority thinks fit.

31 Audits of manufacturing facilities

(1) For the purpose of assessing compliance with the code, the Authority may at any time conduct audits of the manufacturing facilities of any holder of, or applicant for, a licence to manufacture.

(2) The audit may be conducted in any manner that the Authority considers appropriate and consistent with the principles of this Act.

32 Authority may issue compliance notice

The Authority may issue a compliance notice to any person whose manufacturing facilities have been audited under **section 31** requiring the person to do, or refrain from doing, within a specified time, a particular thing that affects the person's compliance with the code or any condition of the licence to manufacture.

33 Deemed compliance with code

A manufacturing facility in which natural health products are manufactured under a licence granted by a recognised authority is deemed to be compliant with the code.

34 Authority may revoke or suspend licence or certificate for non-compliance with code

(1) The Authority may revoke or suspend a licence to manufacture if it is satisfied that the holder of the licence has failed to maintain compliance with the code or any condition of the licence.

(2) The Authority may revoke or suspend an export certificate if it is satisfied that the holder of the certificate has failed to maintain compliance with the code.

Fees

35 Authority may prescribe fees

(1) The Authority may, by notice in the *Gazette*, prescribe fees payable in respect of any notification, application, notice, certification, or audit under this Act.

(2) For the purpose of ensuring that any fee prescribed under **subsection (1)** is proportionate to the cost of the activity to which it relates, the Authority must, no later than 3 years after the commencement of this Act,—

(a) conduct a review of the fees prescribed under **subsection (1)**; and

(b) publish the outcome of the review on an Internet site maintained by or on behalf of the Authority.

Sanctions and penalties

36 Deception

(1) A person commits an offence who, with intent to deceive and for the purpose of obtaining any material benefit or avoiding any material detriment,—

(a) makes any false or misleading statement or any material omission in any notification, application, record, or return for the purpose of this Act, or destroys, cancels, conceals, alters, obliterates, or fails to provide any document, record, return, or information required to be kept or communicated under this Act; or

(b) falsifies, removes, misuses, alters, misapplies, misrepresents, or fails to apply any label of a natural health product; or

(c) misrepresents, substitutes in whole or in part, adulterates, or otherwise tampers with any natural health product so that it no longer matches or complies with its description, label, notification, or health benefit claims; or

(d) falsifies, alters, or misapplies any notification, notice, licence, or declaration attached or relating to a natural health product that is subject to any provision of this Act, or tampers with a natural health product that is subject to such notification, notice, licence, or declaration; or

(e) falsifies, removes, suppresses, or tampers with any samples, test procedures, test results, or evidence taken; or

(f) aids, abets, incites, counsels, procures, or conspires with any other person to commit an offence under this section.

(2) A prosecution for an offence against this section may be proceeded with either summarily or on indictment.

(3) A person who commits an offence against **subsection (1)** is liable,—

(a) in the case of a body corporate, to a fine not exceeding $500,000:

(b) in the case of an individual, to imprisonment for a term not exceeding 5 years and a fine not exceeding $100,000.

37 Sale of natural health products that have not been notified or do not meet standards

(1) A sponsor commits an offence who sells or offers for sale—

(a) any natural health product for which, to the sponsor's knowledge, a product notification has not been completed:

(b) any natural health product that, to the sponsor's knowledge, does not meet—

(i) applicable standards of evidence required for any health benefit claims for the product; or

(ii) applicable standards for labelling or manufacturing.

(2) A sponsor commits an offence who knowingly sells or offers for sale any natural health product that is different in any way from its description in its product notification (for example, the product notification contains additional health benefit claims or the product is manufactured elsewhere).

(3) A prosecution for an offence against this section may be proceeded with either summarily or on indictment.

(4) A sponsor who commits an offence against this section is liable to a fine not exceeding—

(a) $250,000, in the case of a body corporate:

(b) $50,000, in the case of an individual.

38 Manufacturing without licence

(1) A person commits an offence who knowingly manufactures a natural health product in contravention of **section 28(1)**.

(2) A prosecution for an offence against this section may be proceeded with either summarily or on indictment.

(3) A person who commits an offence against this section is liable to a fine not exceeding—

(a) $250,000, in the case of a body corporate:

(b) $50,000, in the case of an individual.

39 Obstruction of authorised person

(1) A person commits an offence who threatens, assaults, or intentionally obstructs or hinders any authorised person who is acting in the performance or exercise of a function, power, or duty that the person is authorised to perform or exercise under **section 46**.

(2) A prosecution for an offence against this section may be proceeded with either summarily or on indictment.

(3) A person who commits an offence against this section is liable to a fine not exceeding—

(a) $250,000, in the case of a body corporate:

(b) $50,000, in the case of an individual.

40 Endangerment of human health

(1) A person commits an offence who, being the manufacturer or sponsor of a natural health product, contravenes or fails to comply with any provision of this Act or of regulations made or any notice given under this Act, knowing that the contravention or failure would or is likely to endanger the health of the public or the health of any individual.

(2) A person commits an offence who, being the manufacturer or sponsor of a natural health product, contravenes or fails to comply with any provision of this Act or of regulations made or any notice given under this Act, knowing that the contravention or failure—

(a) may create, directly or indirectly, a risk to human health; or

(b) may, directly or indirectly, increase the likelihood of an existing risk to human health.

(3) A prosecution for an offence against this section may be proceeded with either summarily or on indictment.

(4) A person who commits an offence against **subsection (1)** is liable,—

(a) in the case of a body corporate, to a fine not exceeding $500,000:

(b) in the case of an individual, to imprisonment for a term not exceeding 5 years and a fine not exceeding $100,000.

(5) A person who commits an offence against **subsection (2)** is liable,—

(a) in the case of a body corporate, to a fine not exceeding $300,000:

(b) in the case of an individual, to imprisonment for a term not exceeding 2 years and a fine not exceeding $75,000.

Disputes

41 Appeals committee

(1) This section establishes the Natural Health Product Appeals Committee.

(2) The appeals committee must consist of 3 members, each appointed by the Minister on any terms and conditions that the Minister thinks fit.

(3) The function of the appeals committee is to determine appeals against decisions of the Authority made by or under this Act.

(4) The appeals committee may, subject to any provision in the regulations relating to the conduct of its proceedings, regulate its own procedure.

42 Appeals

(1) A person who is a party to a decision of the Authority under this Act may appeal against that decision to the appeals committee.

(2) The appeal must be made in the prescribed manner and within the prescribed time.

(3) An appeal on a question of law against a determination of the appeals committee may be made to the High Court in accordance with the rules of court.

Other powers of Authority

43 Statement by Authority

(1) The Authority may, for the purpose of protecting the public, publish statements relating to—

(a) natural health products of any description; or

(b) any matter contained or implied in advertisements, either generally or in any particular advertisement, or

any class or classes of advertisement relating to natural health products of any description.

(2) Every statement published under this section is protected by qualified privilege.

44 Recall of natural health products

(1) If the Authority has good reason to believe that a natural health product is not fit for its intended purpose, or is mislabelled or incorrectly identified, the Authority may, by written notice, require the sponsor of the product to—

(a) arrange for the recall of the product (for example, by issuing recall notices to retailers and consumers); and

(b) dispose of the product.

(2) The notice may specify the time and manner by which the sponsor must arrange for the recall of the product or dispose of the product.

(3) The sponsor must, as soon as practicable, advise the Authority—

(a) of the manner and time in which the sponsor proposes to comply with the notice, unless those matters are already specified in the notice; and

(b) when the notice has been complied with.

45 Delegation

(1) The Authority may, as he or she thinks fit, delegate to any person any of his or her powers, functions, or duties under this Act.

(2) A delegation under **subsection (1)**—

(a) may be made subject to any conditions or restrictions that the Authority thinks appropriate:

(b) may be made generally or in any particular case:

(c) does not prevent the Authority from exercising any power, or carrying out any function or duty:

(d) does not affect the responsibility of the Authority for the actions of any person acting under delegation.

(3) A person who is delegated any powers, functions, or duties under **subsection (1)**—

(a) may, with the prior written approval of the Authority, delegate those powers, functions, or duties to any other person:

(b) may, subject to any conditions or restrictions, exercise those powers, functions, or duties in the same manner and with the same effect as if they had been conferred on that person directly by this Act and not by delegation.

(4) Every person purporting to act under any delegation under **subsection (1)** is, in the absence of proof to the contrary, presumed to be acting in accordance with the terms of the delegation.

Transitional provisions

46 Natural health products before commencement of this Act

(1) This section applies to any product that—

(a) was sold before the commencement of this section; and

(b) complies with **paragraphs (a), (c), and (d)** of the definition of natural health product in **section 6(1)**; and

(c) does not contain (as an ingredient) any substance that does not belong to a class of substance listed in the **Schedule**.

(2) A product to which this section applies may continue to be sold after the commencement of this section if the requirements of **subsection (3)** are met.

(3) The sponsor of a product to which this section applies must ensure that—

(a) the product notification for the product is completed no later than 1 year after the commencement of this section; and

(b) the product complies with labelling requirements set out in regulations made under this Act no later than 2 years after the commencement of this section; and

(c) the manufacture of the product complies with the requirements of this Act (for example, licensing requirements if made in New Zealand) no later than 3 years after the commencement of this section.

Regulations

47 Regulations

(1) The Governor-General may, by Order in Council made on the recommendation of the Minister of Health, make regulations—

(a) amending the **Schedule**:

(b) prescribing the manner in which a product notification for a natural health product must be completed:

(c) prescribing the standards of evidence required to support a health benefit claim:

(d) prescribing the information that must be provided by the sponsor or applicant for the purposes of any application or matter under this Act:

(e) prescribing the criteria by which new ingredients will be assessed:

(f) prescribing requirements for the labelling of natural health products:

(g) specifying any offences that the Authority must take into account for the purposes of **section 29(3)(a)(ii)**:

(h) prescribing the manner in which applications for a licence to manufacture natural health products must be made:

(i) prescribing requirements relating to the manufacture of natural health products:

(j) prescribing the procedure, conduct, and time required for appeals:

(k) prescribing requirements relating to access to the natural health product database, and any other requirements relating to the use of the database:

(l) providing for any other matters contemplated by this Act necessary for its administration, or for giving effect to any provision of this Act.

(2) Before making any recommendation under **subsection (1)**, the Minister must consult with any person or organisation that the Minister considers has an interest in, or will be substantially affected by, the regulations.

(3) Regulations made under **subsection (1)(c)** may require that different levels of health benefit claims may require different levels of evidence.

Review of Act

48 Ministry must review Act

(1) The Ministry of Health must, no later than 5 years after the commencement of this Act,—

(a) conduct a review of the policy of this Act; and

(b) prepare for the Minister of Health a report of the review.

(2) As soon as practicable after receiving the report, the Minister must present a copy to the House of Representatives.

Amendments to Medicines Act 1981

49 Amendments to Medicines Act 1981

Sections 50 to 54 amend the Medicines Act 1981.

50 Interpretation

(1) The definition of **herbal remedy** in section 2(1) is repealed.

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

"**natural health product**—

"(a) has the meaning given to it by **section 6** of the Natural Health Products Act **2011**; or

"(b) means a product that complies in all material respects with the requirements of that section."

51 Meaning of medicine, new medicine, prescription medicine, and restricted medicine

(1) Section 3(1) is amended by inserting "or natural health product" after "medical device".

(2) Section 3(1)(b)(iii) is repealed.

52 Section 28 repealed

Section 28 is repealed.

53 Exemptions for agents and employees

Section 31(1)(c) is repealed.

54 Duty of importer and manufacturer to have and produce specifications of medicines

Section 42(1) is amended by omitting "other than a herbal remedy".

Amendment to Misuse of Drugs Amendment Act 2005

55 Amendment to Misuse of Drugs Amendment Act 2005

Section 56 amends the Misuse of Drugs Amendment Act 2005.

56 Interpretation

Paragraph (b) of the definition of **substance** in section 31 is amended by repealing subparagraphs (iii) and (vi) and substituting the following subparagraph as subparagraph (vi):

"(vi) natural health product (as defined in **section 6** of the Natural Health Products Act **2011**), medicine (as defined in section 3 of the Medicines Act 1981), or related product (as defined in section 94 of Medicines Act 1981):"

Revocation

57 Dietary Supplements Regulations 1985 revoked

The Dietary Supplements Regulations 1985 (SR 1985/208) are revoked.

Schedule ss 5, 20(1), 22(1), 47(1)

Suitable classes of substances

Item	Class of substance
1	A plant or a plant material, an alga, a fungus, a mineral, or a non-human animal material
2	A substance or mixture of substances— (a) obtained by expressions, extraction, distillation, purification, or a traditional preparation of a material described in **item 1**; and (b) not subject to any other process involving chemical transformation other than hydrolysis for preparation of the substance or mixture of substances in an active medicinal form
3	A vitamin or provitamin, including salts and other compounds, of the following types: vitamin A vitamin B1 vitamin B2 vitamin B3 vitamin B5 vitamin B6 vitamin B12 vitamin C vitamin D vitamin E vitamin K biotin choline folic acid
4	A synthetic equivalent of any substance specified in **item 2, 3, or 8**
5	A mineral compound
6	A micro-organism, whole or extracted, except a vaccine
7	Prebiotics

Item	Class of substance
8	Any of the following amino acids: Alanine Arginine Asparagine Aspartic acid Cysteine Glutamic acid Glutamine Glycine Histidine Isoleucine Leucine Lysine Methionine Phenylalanine Proline Serine Threonine Tryptophan Tyrosine Valine

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