Te Aka Whai Ora
Māori Health Authority

Natural health product regulation in the Therapeutic Products Bill: How could this affect rongoā Māori?

Kia ora koutou,

This pānui is for mātanga rongoā, tohunga rongoā and other people who have an interest in rongoā Māori. It is to help you understand what is in the Therapeutic Products Bill, and how sections of the Bill, especially the natural health product regulations, could affect rongoā.

The Therapeutic Products Bill (the Bill) is now being considered by Parliament. This Bill will replace the Medicines Act 1981 and the Dietary Supplements Regulations 1985 with a new law for medicines, medical devices, natural health products and biological 'products' such as blood donations. All of these things are different types of 'therapeutic product'.

The Bill says that therapeutic products will have rules made about who can make them, use them, sell them, advertise them, and what kind of health benefit claims can be said about them. These rules will be made by part of the Ministry of Health, similar to Medsafe, under the leadership of a person called the Regulator. The Regulator has many important functions, including setting standards and approving products, issuing licences for clinical trials, manufacture, pharmacy activities, export and prescribing activities (controlled activities) and engaging with Māori.

The Bill sets out a framework for what kind of rules can be made. However, in many instances the rules themselves will be made after the Bill has become law. This means that the exact nature of the rules (for example, what the product standards will be) has not been decided yet. What the Bill does is give the Regulator the power to make these rules and standards, after undergoing a consultation process with people who are likely to be affected.

Because the Bill is almost 300 pages, Te Aka Whai Ora (the Māori Health Authority) has highlighted sections of the Bill that the rongoā sector may be interested in. Each section in the table below may not include every part of the Bill that is relevant to that topic.

Useful links and resources:

You can read the Beehive press release about the Bill here.

You can follow the progress of the Bill here.

More information about how to make a submission on the Bill will be available soon here.

See a summary of how Bills become laws in **Appendix 1**.

For other areas of the Bill that may be of interest to Māori, see our *Guide to the Therapeutic Products Bill* on our website (or search for rongoā on www.teakawhaiora.nz).

We recommend you read this as well as it covers relevant issues including consultation and the principles for the regulatory framework.

More information about the rongoā work programme of Te Aka Whai Ora is available here.

Although the Therapeutic Products Bill mahi is being led by the Ministry of Health, we have made available an FAQ on the Bill here.

Some useful words to know:

- A Bill is a draft law. Once a Bill has gone through Parliament and been approved, it becomes a law. A law is also called an Act.
- The Bill is broken up into subparts. Each subpart is broken up further into short numbered paragraphs. Each numbered pararaph is usually a 'section'. In the introductory part of this Bill, the sections are referred to as 'clauses'.
- Primary legislation is usually a Bill or an Act. Secondary legislation refers to regulations and rules that can be made after the Bill becomes law.
- A Supplementary Order Paper (SOP) is a paper introduced to Parliament while the Bill is being considered by Parliament, that would make changes to the Bill.
- The Select Committee is a group of MPs (Members of Parliament) who will look at the Bill, hear from members of the public and other groups about what they think about the Bill, and work through any issues. They can also suggest changes are made to the Bill.
- 'Natural health products' are products (for example, kawakawa balm) that are made using one or more ingredients from a list of 'permitted ingredients', and nothing else. The Bill will set out rules for people who make, sell or use natural health products with their patients. Although further work is being undertaken in this area, it is possible that rongoā Māori will be subject to the rules for natural health products.

How could rongoā Māori be affected by the Bill?

The Therapeutic Products Bill introduced to Parliament does not make any specific references to rongoā. This does not mean rongoā is excluded from the Bill. It means that unless changes are made to the Bill at a later date to exclude rongoā, both rongoā rākau and elements of rongoā practice will be regulated by the Bill, under the sections that apply to natural health products.

Whether rongoā will be regulated by the Bill has not yet been decided (see the information below on the Manatū Hauora work programme). It is important to understand that when reading the table below, we have included sections of the Bill that currently apply to rongoā Māori. This is to give you an idea of the potential impact the Bill could have on rongoā *if* changes are not made to the Bill during the Select Committee stage.

What is Te Manatū Hauora (the Ministry of Health) doing?

Te Manatū Hauora (the Ministry of Health) is currently undertaking work to determine how rongoā might be scheduled in legislation. This work will focus on:

- Protection of rongoā
- Patient safety assurance
- Export market access protections (for rongoā practitioners who are exporting rongoā rākau directly to a patient, as well as for manufacturers of rongoā rākau products).

If rongoā is scheduled in legislation this could be done through either a Supplementary Order Paper to the Therapeutic Products Bill, or via a stand alone Rongoā Bill (or both). A Supplementary Order Paper could make changes to the Therapeutic Products Bill to make it clear that rongoā is regulated under natural health products (clarifying the status quo), to

exclude rongoā from some or all of the Therapeutic Products Bill, or to introduce new clauses about rongoā into the Bill. The Ministry is leading targeted engagement with Māori on this mahi.
This work was announced by Minister Henare on 1 December 2022.

To learn more about the Bill, please contact therapeuticproducts@health.govt.nz. To learn more about the engagement process they are undertaking, contact maorihealth@health.govt.nz.

What is Te Aka Whai Ora doing?

Te Aka Whai Ora (the Māori Health Authority) is undertaking a separate programme of work to empower Māori to determine the protection and support needed for the future sustainability of rongoā.

The Te Aka Whai Ora rongoā Māori work programme will be shaped by rongoā practitioners and whānau Māori. It has three key workstreams intended to:

- surface Māori priorities and aspirations for preserving, protecting and supporting rongoā Māori
- understand the mechanisms that are needed within the health system to support those Māori priorities and aspirations for the sustainability and viability of these important services
- identify the funding paths and other resources needed for a sustainable rongoā Māori sector.

If you would like to learn more about the Te Aka Whai Ora rongoā work programme or to be involved in this mahi, please contact rongoa@health.govt.nz.

Areas of the Therapeutic Products Bill that currently apply to rongoā Māori

Natural health products (NHPs)	
Note: page numbers begin at page 1 of the main section of the Bill (the Explanatory note at the front of the Bill has its own page numbers). • **Section 15** Therapeutic purpose (page 28) • **Section 16** Therapeutic product (page 29) • **Section 18** Naturally occurring thing may be product (page 30) • **Section 29** NHPs (page 34) • **Section 30** NHP ingredient, recognised NHP ingredient, and additive or formulation aid (page 35) • **Section 31** Low concentration NHP (page 36) • **Section 190** Misrepresentation about therapeutic product (page 113)	Therapeutic products made from one or more of the ingredients on the natural health product (NHP) ingredient list, and that contain nothing else aside from permitted additives, will be regulated as natural health products. NHP ingredients include plants, plant material, non-human animal material, fungi, microbes, vitamins and minerals. The rules (made after the Bill passes) will list a subset of NHP ingredients as *recognised* NHP ingredients. An NHP will only be able to obtain a **market authorisation** (see Market authorisation section of this table) if its NHP ingredients are limited to those listed as recognised NHP ingredients. The maximum concentration allowed for each NHP ingredient will be also set out in the rules.
Manufacturing natural health products	
• **Section 42** Responsible manufacturer (page 40) • **Section 48** Manufacture of NHP (page 45)	Manufacturing a natural health product includes any part of the process of making the product – such as harvesting and preparing ingredients, testing, labelling or packaging. For example: **48 Manufacture of NHP (page 45)** 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. Manufacturing is a **controlled activity** if done as part of a business or undertaking. **Business or undertaking** is defined in the Bill as "a business, professional practice, or other undertaking, whether or not carried on for gain or reward."
Supplying natural health products	
• **Section 55** Supply (page 48) • **Section 56** Wholesale supply and non-wholesale supply (page 49) • **Section 112** Personalised NHPs (page 76)	To supply a natural health product product means "to supply it to another person who is in New Zealand." If you supply an NHP as part of your business (for example, selling a natural health product) this will usually require market authorisation. Supply does not include administering a NHP directly to a patient. Supply of natural health products is further divided into **wholesale supply** and **non-wholesale supply**. Natural health product practitioners can supply a natural health product to their client if it is non-wholesale supply, and they follow the rules in section 112 (see Personalised NHPs section of this table).
Market authorisation	
• **Section 9** Market authorisations (page 19) • **Section 63** Product standards (page 53) • **Section 67** Market authorisation required to import, supply, or export (page 56)	Market authorisations are generally required for natural health products **imported** into, **supplied** in, or **exported** from New Zealand in the course of business. In order to be granted market authorisation, an applicant must satisfy the Regulator about the safety and quality of the product, and that

• **Section 68** Sponsor's consent required to import product with NZ authorisation • **Section 122** Application for market authorisation for NHP (page 83) • **Section 123** Issue of market authorisation for NHP (page 84) • **Section 124** Criteria for market authorisation of NHP (page 84) • **Section 126** Content of market authorisation (page 85) • **Section 129** Major change results in different product (page 87) • **Section 131** Duration of market authorisation (page 88) • **Section 136** Grounds to cancel market authorisation (page 90) • **Section 351** Use of automated systems (page 181) • **Section 364** Regulator may request further information, site access, etc (page 186) • **Section 368** Regulator may reject non-complying application (page 187)	any proposed health benefit claims are substantiated (see Health benefit claims section of this table). There are two kinds of market authorisation which apply to NHPs: 1. **Standard**, which is the usual authorisation allowing a medicine, a medical device, or an NHP to be imported, supplied, and exported 2. **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. **Issuing market authorisation for NHPs** The Bill allows the Regulator to use automated systems to carry out their functions (see section 351). It is intended that applications for market authorisations for NHPs will be able to be lodged through an online portal with applicants making a declaration that the criteria for an authorisation are met. **Section 63 Product standards (page 53)** This section sets out the rules the Regulator is allowed to make for therapeutic products, including rules about quality and safety, manufacturing, labelling, packaging, product information and consumer information. Product standards are minimum standards that a product must meet before a market authorisation can be issued.
Controlled activities	
• **Section 10** Controlled activities (page 19) • **Section 56** Wholesale supply and non-wholesale supply (page 49) • **Section 69** Controlled activity prohibited unless allowed by licence, permit, or subpart 3 (page 58) • **Section 111** Manufacture and export by sponsor of NHP (page 75)	The Bill will regulate who is allowed to do certain activities involving therapeutic products (called controlled activities) and how those activities can be done. Section 69 sets out the controlled activities for NHPs and states that these will normally require a license or permit: **Section 69 Controlled activity prohibited unless allowed by licence, permit, or subpart 3 (page 57)**

• **Section 112** Personalised NHPs (page 76 – see Personalised NHPs section of this table)	(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: .... (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 However, note that Section 111 allows the sponsor of an NHP **with a market authorisation** to manufacture or export it without needing a licence. In addition, Section 112 allows NHP practitioners to manufacture, supply or export **unauthorised** NHPs to their patients under certain conditions (see Personalised NHPs section of this table).
Supply chain activities	
• **Section 57** Supply chain activity and person in the supply chain (page 49) • **Section 72** Person in supply chain must comply with rules (page 108) • **Section 73** Person in supply chain must comply with qualification, training, and competency requirements (page 59).	This Bill regulates other people who are part of the supply chain for therapeutic products as part of a **business or undertaking**, even if they are not carrying on controlled activities. A business or undertaking is defined in the Bill as "a business, professional practice, or other undertaking, whether or not carried on for gain or reward." For example: **Section 57 Supply chain activity and person in the supply chain (page 49)** (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. **Section 73 Person in supply chain must comply with qualification, training, and competency requirements (page 59)** (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.
Personalised natural health products	
• **Section 56** Wholesale supply and non-wholesale supply (page 49) • **Section 112** Personalised NHPs (page 76)	Section 112 sets out when an NHP practitioner is allowed to manufacture, supply or export a natural health product that does not have market authorisation.

	Section 112 Personalised NHPs (page 76) (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 nonwholesale supply or administer NHPs to address those needs; or (b) the rules say is an NHP practitioner.
Fit and proper person	
• **Section 60** Fit and proper person (page 51)	This section sets out the criteria to be considered a 'fit and proper person' for the purposes of the Bill. Being a 'fit and proper person' is one of the criteria to be a product sponsor (required for market authorisation), to hold a license or permit, or to be a 'responsible person' (someone named on a license, other than the license holder).
Product sponsors	
• **Section 125** Criteria for sponsor of NHP (page 85) • **Section 139** Sponsor must ensure compliance with market authorisation (page 91) • **Section 140** Sponsor must ensure product meets product standards (page 92) • **Section 141** Sponsor must ensure product meets export standards (page 92) • **Section 142** Sponsor must have surveillance and response system (page 92) • **Section 143** Sponsor must comply with rules (page 93) • **Section 144** Sponsor must notify Regulator of certain minor changes (page 93)	Section 125 sets out the criteria for being the sponsor of an NHP, which are the same as for sponsors of medicines and devices. Other clauses set out the responsibilities of product sponsors. For example: **Section 143 Sponsor must comply with rules** This section says the sponsor of a natural health product must comply with any requirements in the rules about any of the following: • the safety and quality of the product • product information and consumer information • identification and labelling • packages and packing: • releasing products for supply: • exporting therapeutic products: • tracing and recall: • record-keeping and auditing:

	• giving information or samples to the Regulator: • the need to have regulatory liaison officers, who may be a regulatory liaison officer, and any other matters relating to them.
Licenses	
• **Section 69** Controlled activity prohibited unless allowed by licence, permit, or subpart 3 (page 57) • **Section 111** Manufacture and export by sponsor of NHP (page 75) • **Section 151** What licence may allow (page 96) • **Section 152** Content of licence (page 96) • **Section 153** Effect of license (page 97) • **Section 157** Criteria for licensee (page 99) • **Section 158** Criteria for granting licence (page 100) • **Section 159** Criteria for responsible person (page 101) • **Section 185** Responsible person must comply with rules (page 111)	Licences allow people to run a business that carries out at least one controlled activity on an ongoing basis. If a person wants to carry out a controlled activity for a short period or to do something on a one-off basis, a permit may be more appropriate. For natural health products that **do not have market authorisation**, a license is needed to: (i) manufacture in the course of a business or undertaking, (ii) export in the course of a business or undertaking: (iii) import a low concentration NHP in the course of a business or undertaking. NHP practitioners can also manufacture and export unathorised NHPs for a particular client, if they follow the rules set out in section 112 (see Personalised NHPs section of this table). Note: a responsible person is someone named in the license who can carry out controlled activities on behalf of the licensee.
Permits	
• **Section 160** What permit may permit (page 101) • **Section 161** Content of permit (page 102) • **Section 165** Criteria for granting permit (page 103) • **Section 166** Duration of licence or permit (page 104) • **Section 167** Conditions on licence or permit (page 105)	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 allow someone in the supply chain to not comply with a normal requirement. A very wide range of matters may be allowed by a permit, in order to allow the Regulator to deal with specific scenarios on a case by case basis.

• **Subpart 4** Obligations of licensees, permit holders, and responsible persons (begins page 109) • **Section 182** Licensee and permit holder must comply with qualification, training, and competency requirements (page 182)	
Health benefit claims	
• **Section 61** Health benefit claim, permitted health benefit claim, and substantiating claims (page 52) • **Section 62** Standard health benefit claims (page 53) • **Section 190** Misrepresentation about therapeutic product (page 113) • **Section 192** Impermissible health benefit claims about NHPs (page 192)	The Regulator will set out a list of standard health benefit claims that can be made about each type of natural health product. Only these pre-approved standard claims can be made about NHPs that do not have market authorisation. When applying for market authorisation, product sponsors can apply to make additional (custom) health benefit claims about the NHP. The Regulator will allow these custom health benefit claims if they are satisfied that the claims can be substantiated. For example: **Section 61 Health benefit claim, permitted health benefit claim, and substantiating claims (page 52)** (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 its market authorisation; or (b) a custom health benefit claim set out in its market authorisation. (3) A permitted health benefit claim for an NHP that does not have s 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.
Advertising	
• **Section 193** Advertisement, communication, and distribute (page 114) • **Section 194** Advertising (page 115) • **Section 326** Orders about advertising, packages, labelling, and identification (page 169)	Section 193 explains what an advertisement for a therapeutic product is and what it means to distribute it. Section 194 sets out the rules for advertising therapeutic products. For natural health products, only products with market authorisation can be advertised. Advertisements can only make approved health benefit claims. There are also a number of other requirements for advertisements.
Prohibitions	
• **Section 33** Prohibited product (page 37) - definition • **Section 71** A person must not administer an NHP to a person by injection or parenteral infusion (page 58) • **Section 74** Prohibited products (page 60) – statute preventing use • **Section 222** Product moratorium order (page 126) • **Section 224** Prohibited product order (page 128) • **Section 216** Premises restriction order (page 125)	For example: **Section 33 Prohibited product (page 37)** The Bill allows the Minister to ban therapeutic products if the Regulator cannot safely manage their risk. See also the Orders and Undertakings section of this table.
Surveillance and monitoring	
• **Section 142** Sponsor must have surveillance and response system (page 92) • **Section 183** Responsible person must report noncompliance (page 110) • **Section 203** Post-market surveillance and response (page 118)	These sections set out the responsibilities for product sponsors and responsible people regarding surveillance and monitoring, as well as the responsibilities and powers of the Regulator.

• **Section 204** Compliance monitoring (page 118) • **Section 206** Power to require person to give information (page 119) • **Section 207** Power to require samples and testing (page 120) • **Section 214** Recall order (page 124) • **Section 239** Exercising powers for enforcement purposes (page 135) • **Section 362** Therapeutic products register (page 185)	
Search and entry related to specific places	
• **Section 208** Power of entry (page 121) • **Section 209** Special requirements at certain places (page 121) – includes marae • **Section 210** Inspector's powers having entered place (page 122) • **Section 216** Premises restriction order (page 125) • **Section 217** Compliance with premises restriction order (page 125) • **Section 240** Entry and search for enforcement purposes (page 135) • **Section 244** Destruction of seized things (page 137) • **Section 327** Forfeiture and seizure (page 169)	For example: **Section 209 Special requirements at certain places (page 121)** This section sets out when and how inspectors can enter and search homes, marae, buildings associated with a marae, and treatment rooms.
Offences	
• **Section 191** Holding out misrepresentation (page 114) • **Secton 192** Impermissible health benefit claims about NHPs (page 114) • **Subpart 2** Offences involving knowledge or recklessness – begins page 138 • **Section 247** Significant risk to personal health or public health—level 1 penalty (page 138) • **Section 248** Significant risk to personal health or public health—level 2 penalty (page 139)	For example: **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

• **Section 250** Offences for misrepresentation about therapeutic product (page 140) • **Section 252** Offence for impermissible health benefit claims about NHPs (page 141) • **Section 253** Offences for unlawful advertising (page 142) • **Section 264** Strict liability offence—level 2 penalty (page 146) – Includes impermissible health benefit claims about NHPs • **Section 265** Strict liability offence—level 3 penalty (page 147) • **Section 267** Civil penalty contravention (page 148) • **Section 276** Infringement offence (page 152)	(b) otherwise, to a fine not exceeding $1 million. **264 Strict liability offence—level 2 penalty (page 146)** Strict liability offences are offences that are committed whether or not the person knew about the law and whether or not the person had a bad intent. There are several offences covered by this section which include (but are not limited to) that people who make therapeutic products (including natural health products) must have the right qualifications, that people must not make unapproved health benefit claims about natural health products, that people must not advertise unauthorised natural health products, and must meet any product standards. Some of these offences would apply to people who make non-commercial (non-authorised) natural health products.
Orders	
• **Subpart 3** Regulatory orders (begins page 124) • **Section 214** Recall order (page 124) • **Section 216** Premises restriction order (page 125) • **Section 218** Advertising remediation order (page 125) • **Section 220** Directions order (page 126) • **Section 222** Product moratorium order (page 126) • **Section 230** Content of regulatory orders (page 131)	The Regulator can make a range of different orders to address safety issues arising after a therapeutic product enters the supply chain, including recall orders, advertising remediation orders, directions orders, and product moratorium orders.
Cost recovery	
• **Section 325** Order person to pay costs of mitigating risk or dealing with product (page 169) • **Section 334** Recovery of costs (page 173) • **Section 335** Principles for cost recovery (page 174)	These sections set out the principles and methods for setting fees and levies as part of cost recovery for the Regulator.

• **Section 337** Methods of setting fees and levies (page 174) • **Section 339** Preconditions for making regulations imposing fees or levies (page 175) • **Section 341** Three-yearly review of cost recovery (page 176)	
Transitional provisions	
Schedule 1 (starts page 202) – section numbering starts again from 1 • **Section 6** Product that was consented medicine but is now NHP—deemed to be medicine (page 207) • **Section 12** NHPs—temporary market authorisation created (page 211) • **Section 27** Licences for activities with medical device, or product not regulated, under 1981 Act (page 217) • **Section 28** Licences created in relation to controlled activities with NHP (page 217) • **Section 28** Licences created in relation to controlled activities with NHP (page 217)	Transitional provisions grant temporary permissions (for example, temporary market authorisation, or a temporary license) that expire after a certain length of time. This is to give people time to apply for the regulatory approvals they will need under the new Therapeutic Products regime. For example: **Section 28 Licences created in relation to controlled activities with NHP (page 217)** (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 doing immediately before commencement. (4) However if, immediately before commencement, the product was a food (as defined in section 9of 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.

Appendix 1: How a Bill becomes law