Departmental Disclosure Statement

Therapeutic Products Bill

The departmental disclosure statement for a government Bill seeks to bring together in one place a range of information to support and enhance the Parliamentary and public scrutiny of that Bill.

It identifies:

- the general policy intent of the Bill and other background policy material;
- some of the key quality assurance products and processes used to develop and test the content of the Bill;
- the presence of certain significant powers or features in the Bill that might be of particular Parliamentary or public interest and warrant an explanation.

This supplementary disclosure statement was prepared by Manatū Hauora | The Ministry of Health to reflect changes to the Therapeutic Products Bill made since it was introduced to Parliament on 30 November 2022. It replaces the previous disclosure statement.

Changes to the previous statement include:

- amendments to the General Policy Statement to reflect that the revised purpose of the Bill is to ensure the substantiation of natural health product health benefit claims; and to reflect changes made by the supplementary order paper in relation to small-scale natural health product producers, and rongoā.
- part 2.1 to add two post-introduction literature reviews
- part 2.3, 2.3.1, and 2.3.2 to add a new regulatory impact analysis
- part 2.4 to add two post-introduction literature reviews
- part 3.2 to reflect changes post-introduction to address consistency with Treaty of Waitangi obligations
- part 3.6 to add the rongoā workstream
- part 3.7 to add advice sought from Te Arawhiti
- part 4.7 to address new powers of the Bill in relation to exemptions
- part 4.9 to discuss the special provision for rongoā.

The Ministry of Health certifies that, to the best of its knowledge and understanding, the information provided is complete and accurate at the date of finalisation below.

18 July 2023

Contents

Part One: General Policy Statement

Overview

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

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

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

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

Background

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

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

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

Purpose

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

- acceptable safety, quality, and efficacy or performance of medicines, medical devices, and active pharmaceutical ingredients across their lifecycle; and
- acceptable safety and quality of natural health products across their lifecycle, and the substantiation of health benefit claims.

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

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

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

- providing vitamin, mineral, or other human nutritional supplementation:
- maintaining or promoting health.

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

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

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

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

Omnibus Bill

The Bill is an omnibus Bill introduced in accordance with Standing Order 267(1)(a). That Standing Order provides that an omnibus Bill to amend more than 1 Act may be introduced if the amendments deal with an interrelated topic that can be regarded as implementing a single broad policy. That policy is to give effect to the Bill's purpose and guiding principles so as to regulate therapeutic products across their lifecycle.

Market Authorisations

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

Market authorisations for medicines and medical devices are issued following an evaluation by the Regulator of a product's safety, quality, and efficacy or performance. The Bill empowers the creation of risk-proportionate approval pathways and the setting of relevant product standards. The Bill also allows products without a market authorisation to be imported into and supplied in New Zealand in limited circumstances. Controls on this activity will be set out in secondary legislation. Some products, notably low-concentration natural health products, some rongoā products and certain natural heath products made by small-scale producers, will not require a market authorisation before supply.

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

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

Controlled activities and other activities involving therapeutic products

The Bill provides for the regulation of a range of controlled activities. For medicines and medical devices, controls are imposed on, among other, manufacturing, wholesale and non-wholesale supply, exporting, and conducting a clinical trial with the product. Additional controls are placed on the use of medicines, including prescribing, compounding, dispensing, and administering. Manufacturing and exporting a natural health product in the course of business are controlled activities, as is carrying on a pharmacy business. Provisions in the Bill enable 'customised' natural health products and natural health products used in rongoā activities to be manufactured by a 'NHP practitioner' or 'rongoā practitioner', respectively, without the practitioner needing to apply for a manufacturing licence.

While advertising is not a controlled activity, the Bill allows the regulator to impose restrictions on advertising of therapeutic products, these regulations can have the effect of prohibiting specific advertising practices in specific circumstances (eg, advertising to children, advertising classes of products to the general public).

Regulator and regulatory matters

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

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

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

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

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

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

Effects on other legislation and statutory regimes

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

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

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

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

Part Two: Background Material and Policy Information

Published reviews or evaluations

2.1. Are there any publicly available inquiry, review or evaluation reports that have informed, or are relevant to, the policy to be given effect by this Bill?	**YES**
Literature Review: *Rapid literature review – Impact of direct-to-consumer advertising of prescription medicines* – produced by Sapere Research Group, 5 April 2023. Literature Review: *Rapid literature review – Evidence of harm in relation to the use of natural health products* – produced by Sapere Research Group, 5 April 2023. These are accessible at https://www.parliament.nz/en/pb/sc/scl/health/tab/submissionsandadvice as Ministry of Health (Departmental Report - Appendix 6) and as Ministry of Health (Departmental Report - Appendix 7).	

Relevant international treaties

2.2. Does this Bill seek to give effect to New Zealand action in relation to an international treaty?	**YES**
Subpart 3 of Part 4 of the Bill gives effect to New Zealand's World Trade Organization (WTO) obligations and obligations under the New Zealand-United Kingdom Free Trade Agreement (NZ-UK FTA) and the New Zealand-European Union Free Trade Agreement (NZ-EU FTA) (when each of those FTAs enter into force) to protect the confidentiality of 'active ingredient information about innovative medicines.' These provisions are commonly referred to as 'data protection' provisions. Data protection provisions impose additional requirements on how and when the regulator can use information submitted as part of the first application for a medicine that contains a novel active ingredient. These provisions reflect similar provisions in the current Medicines Act 1981 and apply only in relation to medicines.	

2.2.1. If so, was a National Interest Analysis report prepared to inform a Parliamentary examination of the proposed New Zealand action in relation to the treaty?	**N/A**
The Bill carries over previous provisions in the Medicines Act 1981 that were enacted in 1995 to meet New Zealand's WTO obligations. New Zealand's obligations under the NZ-UK FTA were commented on in a recent National Interest Analyses. See for example: https://www.mfat.govt.nz/assets/Trade-agreements/UK-NZ-FTA/NZ-UK-FTA-National-Interest-Analysis.pdf	

Regulatory impact analysis

2.3. Were any regulatory impact statements provided to inform the policy decisions that led to this Bill?	**YES**

The following regulatory impact statements have been provided:

Regulatory Impact Assessment: *Therapeutic Products Regulation - Replacement of Medicines Act 1981 and Medicines Regulations 1984 with a new legislative scheme for therapeutic products (for Cabinet papers 1 and 2)*, 7 November 2018

Regulatory Impact Assessment: *Therapeutic Products Regulation - Replacement of Medicines Act 1981 and Medicines Regulations 1984 with a new legislative scheme for therapeutic products - Analysis of specific issues and options*, 7 November 2018

Regulatory Impact Assessment: *Therapeutic Products Bill - Personal import of Medicine by mail/courier*, 18 December 2018

These are accessible at https://www.dpmc.govt.nz/publications and can also be found and downloaded at http://www.treasury.govt.nz/publications/informationreleases/ris.

Regulatory Impact Statement: *Pharmacy ownership and licensing*, 21 May 2021

Regulatory Impact Statement: *Regulating natural health products*, 20 May 2021

Regulatory Impact Statement: *Therapeutic and Natural Health Products Regulation – Supplementary Analysis 2022 No 1 (Civil Pecuniary Penalties and Crown Liability)*, 4 November 2022

Regulatory Impact Statement: *Therapeutic and Natural Health Products Regulation – Supplementary Analysis 2022 No. 2 (Entity Form and Funding)*, 4 November 2022

Regulatory Impact Statement: *The regulation of rongoā and small-scale producers of natural health products under the Therapeutic Products Bill*, 10 May 2023

These are accessible at https://www.health.govt.nz/about-ministry/information-releases/regulatory-impact-statements and from http://www.treasury.govt.nz/publications/informationreleases/ris.

Some content is withheld to protect the confidentiality of advice tendered by Ministers of the Crown and officials.

2.3.1. If so, did the RIA Team in the Treasury provide an independent opinion on the quality of any of these regulatory impact statements?	**YES**

Regulatory Impact Assessment: "*Therapeutic Products Regulation - Replacement of Medicines Act 1981 and Medicines Regulations 1984 with a new legislative scheme for therapeutic products (for Cabinet papers 1 and 2)*". The Regulatory Impact Analysis Team considered that the RIS met the quality assurance criteria.

Regulatory Impact Assessment: "*Therapeutic Products Regulation - Replacement of Medicines Act 1981 and Medicines Regulations 1984 with a new legislative scheme for therapeutic products - Analysis of specific issues and options*". The Regulatory Impact Analysis Team considered that the RIS met the quality assurance criteria.

The Ministry of Health and the Regulatory Quality Team at the Treasury reviewed the Regulatory Impact Assessment (RIA) "*Therapeutic Products Bill – Personal import of Medicine by mail/courier*" produced by the Ministry of Health and dated November 2018.

"The review team considers that it met the Quality Assurance criteria. The analysis is commensurate with the scale of the issue. While there are some uncertainties about the scale of the problem, as identified in the analysis, this proposal will form part of the consultation on the exposure draft of the wider Therapeutic Products Bill. We expect any insights gained from this consultation will inform revised analysis."

The Ministry of Health QA panel reviewed the Impact Statement titled "*Pharmacy ownership and licensing*", produced by the Ministry of Health and dated 21 May 2021. "The panel considers that the Impact Statement meets the quality assurance criteria. The Impact Statement is clear, concise, consulted, complete and convincing. The analysis addresses the decisions sought from Cabinet, is balanced in its presentation of the information and the major impacts are identified and assessed."

The Ministry of Health QA panel reviewed the Impact Statement titled "*Regulating Natural Health Products*", produced by the Ministry of Health and dated 20 May 2021. "The panel considers that the Impact Statement meets the quality assurance criteria. The Impact Statement is clear, concise, consulted, complete and convincing. The analysis addresses the decisions sought from Cabinet, is balanced in its presentation of the information and the major impacts are identified and assessed."

The Ministry of Health QA panel reviewed the Impact Statement titled *"Therapeutic and Natural Health Products Regulation – Supplementary Analysis 2022 No 1."* relating to civil pecuniary penalties and Crown liability. The panel considers that the Impact Statement "meets the quality assurance criteria, and the analysis was clear and concise, and the analysis convincing."

The Ministry of Health QA panel reviewed the Impact Statement titled *"Therapeutic and Natural Health Products Regulation – Supplementary Analysis 2022 No 2"* relating to the form of the regulator and cost-recovery options. The panel considered that the Impact Statement "partially meets the quality assurance criteria. While the paper meets most of the criteria, the Committee considered that there could have been further clarification to make the analysis and scoring of the options more robust." "Both reports partially meet the quality assurance criteria. While the committee was comfortable with the options analysis undertaken, it considered that both papers could be clearer and more concise."

The Ministry of Health QA panel reviewed the Impact Statement titled *"The regulation of rongoā and small-scale producers of natural health products under the Therapeutic Products Bill",* produced by the Ministry of Health and dated 10 May 2023. The panel considered that the Impact Statement "partially meets the quality assurance criteria". "While the analysis in respect to small-scale NHP manufacturers was clear and convincing, the rongoā proposals would have benefitted from further clarity and information, such as further detail on the Rongoā Advisory Committee and to what extent Māori will influence appointments."

2.3.2. Are there aspects of the policy to be given effect by this Bill that were not addressed by, or that now vary materially from, the policy options analysed in these regulatory impact statements?	**YES**

The regulatory impact statement for pharmacy ownership reflects the long-term policy position to remove ownership restrictions and support the health system reform objectives of addressing gaps to access and health outcomes.

The Bill retains the existing restrictions in the Medicines Act, including the exemption mechanism, to enable the pharmacy sector to integrate the new structural, accountability, and funding changes in the transformed health system and continue to meet the needs of the COVID-19 response. Continuing with the status quo will not jeopardise the ongoing provision of safe and effective medicines and other therapeutic products.

The regulatory impact statement for the regulation of small-scale natural health product producers recommended the retention of the status quo (ie, that that Bill as introduced remain unchanged). In contrast, the Government's supplementary order paper will disapply provisions in the Bill in relation to certain small-scale natural health producers. These provisions relate to disapplying market authorisation and manufacturing licensing requirements. Disapplying these requirements is justified on the basis that the risk profile for natural health products, when combined with small-scale distribution, suggest these products are unlikely to pose a significant public health risk. While a literature review on harms associated with the use of natural health products (referred to in 2.1 above) did not specifically search for literature on the risk of adverse events from different sized natural health product manufacturers, this topic did not arise as an issue in the papers reviewed.

Extent of impact analysis available

2.4. Has further impact analysis become available for any aspects of the policy to be given effect by this Bill?	**YES**

The supplementary regulatory impact statements undertaken in 2021 was an opportunity to revisit the analyses conducted in 2015 and 2016. These matters include the offence and penalty regime, particularly the addition of civil pecuniary penalties and Crown liability, the entity form of the regulator, and the cost-recovery settings.

Additional literature reviews were undertaken in 2023 in relation to direct-to-consumer advertising of prescription medicines (DTCA-PM), and evidence of harms associated with the use of natural health products. The DTCA-PM review did not result in a change in the Bill to explicitly ban DTCA-PM outright. The natural health products review helped to support the proposed supplementary order paper on small-scale producers of natural health products, and rongoā.

Rongoā aspects of the supplementary order paper were informed by a separate rongoā workstream led by Manatū Hauora between December 2022 and March 2023.

2.5. For the policy to be given effect by this Bill, is there analysis available on:	
(a) the size of the potential costs and benefits?	**YES**
(b) the potential for any group of persons to suffer a substantial unavoidable loss of income or wealth?	**YES**

The regulatory impact statement for the development of the draft exposure Therapeutic Products Bill in 2018/19 undertook multi-criteria analyses in lieu of cost-benefit analyses. This was due to the existing established regulatory regime under the Medicines Act 1981, and that the potential costs or benefits were likely to be impacted by the level of effective compliance or non-compliance.

The 2021 regulatory impact statement for the inclusion of natural health products in the therapeutics regime analysed the potential costs and benefits for regulating this sector, which to date has not been regulated holistically.

2.6. For the policy to be given effect by this Bill, are the potential costs or benefits likely to be impacted by:	
(a) the level of effective compliance or non-compliance with applicable obligations or standards?	**YES**
(b) the nature and level of regulator effort put into encouraging or securing compliance?	**YES**

Part Three: Testing of Legislative Content

Consistency with New Zealand's international obligations

3.1. What steps have been taken to determine whether the policy to be given effect by this Bill is consistent with New Zealand's international obligations?

The policy in the Bill and supplementary order paper is consistent with New Zealand's international obligations.

Specific regard has been taken on advice from the Ministry of Foreign Affairs and Trade, and the Ministry of Business, Innovation and Employment on New Zealand's obligations relating to quantitative restrictions under the World Trade Organization (WTO) General Agreement on Tariffs and Trade, technical barriers to trade under the WTO Agreement on Technical Barriers to Trade, data protection for novel medicines under the NZ-UK FTA and the NZ-EU FTA, other intellectual property matters and trans-Tasman commitments.

The Ministry has taken into account New Zealand's obligations under the United Nations Declaration on the Rights of Indigenous People.

These obligations will be relevant considerations during the design of secondary legislation. We will work with agencies to ensure these are consistent with New Zealand's international obligations.

Consistency with the government's Treaty of Waitangi obligations

3.2. What steps have been taken to determine whether the policy to be given effect by this Bill is consistent with the principles of the Treaty of Waitangi?

An exposure draft of the Bill underwent public consultation between December 2018 and April 2019. Māori health providers were invited to a series of general sector forums held in 2019. In 2022, the Ministry engaged specifically with Māori clinicians and health providers on the Bill.

Te Aka Whai Ora – the Māori Health Authority, Te Arawhiti and Te Puni Kōkiri have been consulted on the Bill and the supplementary order paper. Advice on proposals to reflect the principles of Te Tiriti o Waitangi (Te Tiriti) in the Bill was developed between the Ministry and Te Aka Whai Ora, with external advice provided by Te Arawhiti and the Treaty Provisions Oversight Group. Te Aka Whai Ora supported stronger Te Tiriti clauses in the Bill including reference to the articles of Te Tiriti, and the specific exclusion of rongoā from the Bill. Te Puni Kōkiri also supported the exclusion of rongoā.

The Ministry conducted an analysis of the Bill against the health sector principles set out in the Pae Ora (Healthy Futures) Act 2022. Those principles aim to incorporate key concepts discussed by the Waitangi Tribunal in *Hauora: Report on Stage One of the Health Services and Outcomes Kaupapa Inquiry (Wai 2575)*. Provisions of the Bill relating to decision making principles, review panels, consultation requirements and the functions of the regulator were drafted to be consistent with these principles.

In 2022, the relationship of the Bill to rongoā Māori was explored through a series of wānanga and hui involving a representative from a peak governance group for rongoā practitioners, and officials from Te Aka Whai Ora and wider Ministry.

Between December 2022 and March 2023, a rongoā workstream was conducted by the Ministry to analyse the Therapeutic Products Bill to identify any gaps and opportunities to protect rongoā, assure whānau safety, and ensure access to the export market for rongoā practitioners.

Consistency with the New Zealand Bill of Rights Act 1990

3.3. Has advice been provided to the Attorney-General on whether any provisions of this Bill appear to limit any of the rights and freedoms affirmed in the New Zealand Bill of Rights Act 1990?	**YES**
The draft Bill was sent to the Ministry of Justice in order for them to prepare advice on consistency with the New Zealand Bill of Rights Act 1990. The Ministry of Justice concluded that the Bill appears to be consistent with the rights and freedoms affirmed in the Bill of Rights Act. A copy of the advice is accessible on the Ministry of Justice website at https://www.justice.govt.nz/assets/20221201-Therapeutic-Products-Bill.pdf.	

Offences, penalties and court jurisdictions

3.4. Does this Bill create, amend, or remove:	
(a) offences or penalties (including infringement offences or penalties and civil pecuniary penalty regimes)?	**YES**
(b) the jurisdiction of a court or tribunal (including rights to judicial review or rights of appeal)?	**NO**
The Bill includes a hierarchy of enforcement tools, including tiered criminal offences, enforceable undertakings, infringement notices, and a civil pecuniary penalty regime. This ensures proportionate enforcement action can be taken for the breadth of conduct and actors in the therapeutic products regime.	

3.4.1. Was the Ministry of Justice consulted about these provisions?	**YES**
The Offence and Penalty Vetting team at the Ministry of Justice was consulted on the Bill's offence and penalty regime, including the inclusion of a civil pecuniary penalty regime and extension of criminal liability to the Crown. The Ministry of Justice is satisfied with the Bill's offence and penalty provisions.	

Privacy issues

3.5. Does this Bill create, amend or remove any provisions relating to the collection, storage, access to, correction of, use or disclosure of personal information?	**YES**
The Bill contains several clauses (for example, clause 206) which override the Privacy Act 2020. In addition, the Bill contains a regulation making power which would allow the regulator to make regulations that override the Privacy Act. In general, most information collected and used by the regulator will relate to commercial actors in the therapeutic product supply chain or practitioners involved in supplying or administering those products. The Bill contains provisions that provide for protections on the sharing of personal information, particularly with overseas organisations.	

3.5.1. Was the Privacy Commissioner consulted about these provisions?	**YES**
The Privacy Commissioner raised some initial concerns about the breadth of these overrides and will work with officials to address these, following introduction of the Bill and during the development of secondary legislation to enable the new regulatory regime.	

External consultation

3.6. Has there been any external consultation on the policy to be given effect by this Bill, or on a draft of this Bill?	YES
An exposure draft Bill that did not include natural health products was publicly released in December 2018. Consultation on the exposure Bill ended in April 2019. The Natural Health Products Bill, which lapsed in 2017, underwent significant consultation including at select committee. Inclusion of natural health products in the Therapeutic Products Bill builds on from the policy. Stakeholder engagement on the Bill and underlying policy has been ongoing since April 2019, with delays and disruption resulting from COVID-19. Engagement has involved industry, practitioners and relevant academics. The policy, to be given effect to by the supplementary order paper, was informed by submissions on the Bill to the Health Committee and the separate rongoā workstream, which was established on 30 November 2022. The rongoā workstream explored gaps and opportunities in the Bill for rongoā and provided advice about the protection of rongoā, assurance of patient safety and protecting export market access.	

Other testing of proposals

3.7. Have the policy details to be given effect by this Bill been otherwise tested or assessed in any way to ensure the Bill's provisions are workable and complete?	YES
Advice on the Bill has been sought from the current regulator, Medsafe. Policy advice has been sought from industry, practitioners and Crown organisations involved in supply chain activities (e.g., NZ Blood and Organ Service and Te Whatu Ora). Advice on the supplementary order paper was sought from Crown Law and the Treaty Provision Oversight Group with Te Arawhiti.	

Part Four: Significant Legislative Features

Compulsory acquisition of private property

4.1. Does this Bill contain any provisions that could result in the compulsory acquisition of private property?	**NO**

Charges in the nature of a tax

4.2. Does this Bill create or amend a power to impose a fee, levy or charge in the nature of a tax?	**YES**

The Bill retains and extends (because of the broader range of products and activities regulated) the current cost-recovery model for the regulator by way of charging fees for regulator activities such as:

- Approval, accreditation and certification activities
- Audits of individual businesses
- Export certification.

In addition, the Bill provides for the collection of levies from industry participants to contribute to those regulator activities which have some public good element, but also benefit a defined group of participants or risk-makers ('club goods'). The ability to raise levies is a change from the Medicines Act and means that industry participants will equitably pay their share of the costs of regulator activities such as:

- monitoring and testing compliance
- developing and maintaining market access for therapeutic product exporters.

The Bill provides safeguards on the level and extent of fees and levies charged through:

- the inclusion of a set of principles for cost recovery that state that any fees or levies must be equitable, efficient, justifiable and transparent
- the requirement that they be set by way of secondary legislation (regulations and rules), which ensures that the public is consulted and that the fee or levy is subject to scrutiny by Cabinet.

Retrospective effect

4.3. Does this Bill affect rights, freedoms, or impose obligations, retrospectively?	**NO**

Strict liability or reversal of the usual burden of proof for offences

4.4. Does this Bill:	
(a) create or amend a strict or absolute liability offence?	YES
(b) reverse or modify the usual burden of proof for an offence or a civil pecuniary penalty proceeding?	YES

The Bill includes multiple strict liability provisions. This is consistent with comparable international legislation in this domain and also consistent with other domestic regulatory regimes, such as the Food Act 2014. The design of these provisions is consistent with Legislation Design and Advisory Committee guidelines on the use of strict liability offences and the provisions have been reviewed by the Ministry of Justice.

Specific defences (in addition to common law defences) are available to those charged with a strict liability offence. There are no absolute liability offences.

The Bill includes a civil pecuniary penalty regime, which is limited to contraventions that occur in the course of business, or to make a commercial gain or avoid a commercial loss.

The Bill includes provisions that attribute the conduct of workers up to senior managers and attribute the state of mind of senior managers, workers or agents to a corporate entity. Contraventions committed by a body corporate can be attributed downward to senior managers. Specific defences are available – including a defence of reasonable steps.

The Bill provides for a range of evidentiary matters. These include, *inter alia*:

- not requiring proof that a *specific* individual was in fact exposed to a significant risk of death or serious injury or serious illness (i.e., where one of the elements of the offence is that a person knows that, or is reckless as to whether, their conduct exposes any individual to such a risk)
- not requiring proof that a person knew that a medicine was a prescription medicine where that person unlawfully supplied by non-wholesale supply, a prescription medicine
- providing that certain content in regulatory orders related to the existence of a specified risk is *prima facie* evidence of that risk and the consequences of that risk
- allowing for certain presumptions to be drawn from labels, samples and evidence of testing.

The Offence and Penalty Vetting team at the Ministry of Justice was consulted on the Bill's offence and penalty regime, including these presumptions and is satisfied with the Bill's offence and penalty provisions. The evidentiary matters listed above are consistent with existing provisions in the Medicines Act 1981 and similar regulatory regimes, such as the Food Act 2014. None of the provisions reverse the legal burden of proof and all presumptions are rebuttable.

The supplementary order paper does not create any new offences.

Civil or criminal immunity

4.5. Does this Bill create or amend a civil or criminal immunity for any person?	YES

The Bill will extend criminal liability to the Crown, and Crown organisations and employees will be liable for contraventions of the Act and regulations. The regulator will be able to issue injunctions against Crown organisations and Crown employees.

The Bill at clause 236 grants civil and criminal immunity for the regulator, the Crown, or any other person acting on behalf of the regulator, for making public safety announcements for the purpose of protecting, promoting, and improving personal health or public health.

Significant decision-making powers

4.6. Does this Bill create or amend a decision-making power to make a determination about a person's rights, obligations, or interests protected or recognised by law, and that could have a significant impact on those rights, obligations, or interests?	**YES**
The Bill creates a requirement for all therapeutic products to receive an authorisation (or other permission) before they can be supplied in, exported from or imported to New Zealand. Many permissions under the Bill are operationalised via a system of market authorisations, licences, permits and standing permissions in the Bill (including a personal importation provision). A decision to cancel or suspend a market authorisation, licence or permit (or to not issue one to a person) may result in a significant impact on an individual's interests. Some interests, particularly in relation to the practice of rongoā and traditional health practices that are part of a community's religious practices, may be recognised or protected under law, including the Bill of Rights Act 1990. As the Bill does not empower the making of secondary legislation that is inconsistent with the Bill or Rights 1990, any limitations on rights protected under the Bill of Rights Act 1990 will need to be justified and reasonable.	

Powers to make delegated legislation

4.7. Does this Bill create or amend a power to make delegated legislation that could amend an Act, define the meaning of a term in an Act, or grant an exemption from an Act or delegated legislation?	**YES**
Clause 379 allows the Regulator to exempt a specific therapeutic product, class of products or things from the application of any provision in the Bill. Likewise, the Regulator can exempt a class of persons from compliance with any provision in the Bill. This exemption power is subject to a statutory test for use and procedural safeguards, including consultation and publication requirements. An exemption expires no later than 5 years from the date on which it comes into force. The supplementary order paper will amend the Bill to create a new power for the Minister, by regulations, to disapply provisions of the Bill relating to the requirements to obtain market authorisation or manufacturing licences for products made by certain small-scale producers of natural health products, for non-wholesale supply in New Zealand.	

4.8. Does this Bill create or amend any other powers to make delegated legislation?	**YES**
Clause 375 provides for regulations to be made by the Governor-General by Order in Council. These will provide for the matters of detail necessary to give full effect to the Act.	

Any other unusual provisions or features

4.9. Does this Bill contain any provisions (other than those noted above) that are unusual or call for special comment?	**YES**
The supplementary order paper will amend the Bill to create a provision regarding rongoā. This provision would remove requirements in the Bill for rongoā practitioners to obtain a manufacturing licence or market authorisation for natural health products made and supplied for rongoā services and activities, with exception of rongoā products produced for commercial wholesale or commercial export. This provision is intended to provide for the Crown's obligations under Te Tiriti in relation to the practice of rongoā. The provision will also establish a rongoā advisory committee to provide advice to the regulator on matters related to rongoā, including whether an individual or activity falls within the scope of the exemption.	