NEW ZEALAND
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13 February 2023

Personal details removed for proactive release

OIA28448

Tēnā koe Personal details removed for proactive release

I refer to your email of 29 January 2023 in which you request the following under the Official Information Act 1982 (OIA):

> *Any advice provided by MFAT relating to the alignment of the Therapeutic Products Bill with international standards, trade-related requirements, including any references to the Crown's Tiriti o Waitangi obligations and related protections in such agreements.*

The attached documents are relevant to your request. We have withheld parts of these documents under the following sections of the OIA:

- 6(a): to avoid prejudicing the security or defence of New Zealand or the international relations of the New Zealand Government;
- 9(2)(a): to protect individuals' privacy; and
- 9(2)(h): to maintain legal professional privilege.

Additionally, some information is being withheld in full under the following sections of the OIA:

- 9(2)(g)(i): to protect the free and frank expression of opinions by departments;
- 9(2)(f)(iv): to protect the confidentiality of advice tendered by Ministers of the Crown and officials; and
- 9(2)(h): to maintain legal professional privilege.

Documents withheld in Full	
Date	**Document Description**
11-13 October 2022	Email chain from Ministry of Foreign Affairs and Trade (MFAT) to the Ministry of Health (MoH).
3 November 2022.	Email from MFAT to MoH.
	Draft Therapeutic Products Bill: Approval for Introduction
	Therapeutic Products Bill: Government Bill

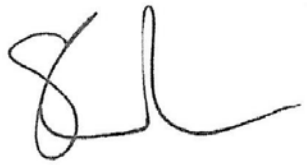
Please be aware that your request relates in part to legal advice on international obligations that have been withheld as legally privileged.

Where the information has been withheld under section 9 of the OIA, we have identified no public interest in releasing the information that would override the reasons for withholding it.

Please note that we may publish this letter (with your personal details redacted) and enclosed documents on the Ministry's website.

If you have any questions about this decision, you can contact us by email at: DM-ESD@mfat.govt.nz. You have the right to seek an investigation and review by the Ombudsman of this decision by contacting www.ombudsman.parliament.nz or freephone 0800 802 602.

Nāku noa, nā



Sarah Corbett
for Secretary of Foreign Affairs and Trade

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 disclosure statement was prepared by Manatū Hauora – The Ministry of Health.

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.

[Date finalised].

Contents

Part One: General Policy Statement

Overview

The Therapeutic Products Bill (the Bill) is intended to replace the current Medicines Act 1981 (Medicines Act) and Dietary Supplements Regulations 1985 (under the Food Act 2014) 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 biolcgical 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 and mineral supplements. Therapeutic products are used by all New Zealanders in their everyday lives and in all parts of the health system.

Background

Currently, the Medicines Act 1981 (Medicines Act) is the primary legislation for enabling access to safe medicines and medical devices. The Medicines Act is outdated and does not provide coverage of the many products used in modern healthcare delivery. Likewise, the current regulatory arrangements for natural health products cannot provide an appropriate level of assurance that products imported and supplied in New Zealand are safe or made to the appropriate quality standards, nor do they allow for a range of evidence-based health benefit claims. New Zealand's exporters also suffer from the lack of a modern and flexible regime.

Purpose

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

(a) acceptable safety, quality, and efficacy or performance of medicines, medical devices, and active pharmaceutical ingredients across their lifecycle; and

(b) acceptable safety and quality of natural health products across their lifecycle.

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

In terms of the health benefits, a therapeutic product is one that is intended to be used by humans for a therapeutic purpose. This includes, but is not limited to:

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

While the above can provide for enormous benefits, therapeutic products are not risk-free. The ingredients used in a product may be inherently unsafe (e.g., many chemotherapies kill all the cells that are growing fast—even normal cells), harmful in large amounts (e.g., some fat-soluble vitamins can result in toxicity) or present unique risks to different groups, such as pregnant people, infants or those taking other medicines.

Risks can also arise during a product's manufacture, such as the risk of contamination with pathogens or other substances, including counterfeits. The effectiveness or safety of products can be affected by improper handling and transportation, and inappropriate supply, administration or, in the case of medical devices, use by unqualified people.

Other guiding principles are important in helping achieve the Bill's aim. Regulation of therapeutic products should support timely access to products, an open and well-functioning market, and innovation. Regulation should be administered in an open and transparent manner

and there should be co-operation with overseas regulators, compliance with international obligations, and, if appropriate, alignment with international standards and practice.

In essence, the Bill's aim and guiding principles result in therapeutic products being regulated across their lifecycle and obligations being imposed on individuals involved in a product's supply chain.

Market Authorisation

As a central principle, the Bill establishes a requirement that therapeutic products must receive a market authorisation before they can be imported into, exported from or supplied in New Zealand. Significant risk-based, relevant penalties attach to the unlawful importation, supply and export of therapeutic products.

Market authorisations for medicines and medical devices are granted if an evaluation by the regulator of a product's safety, quality and efficacy or performance is approved. The Bill empowers the creation of risk-proportionate approval pathways via secondary legislation and the determination of relevant product standards. The Bill also provides for narrow mechanisms to allow for the importation and supply within New Zealand of products without a market authorisation. Controls on this activity will be set out in secondary legislation.

Natural health products imported into, supplied in and exported from New Zealand in the course of business will require a market authorisation issued by the regulator. Reflecting their generally lower-risk, natural health products will be evaluated to different standards than those for medicines and most medical devices with high to intermediate risks.

The Bill allows the regulator to issue an export market authorisation for a product that may not meet one or more criteria for a product supplied in or imported into New Zealand. This is intended to support the export of safe, quality products from New Zealand to overseas markets that have product approval requirements for therapeutic products that differ from those of New Zealand.

The Bill calls a person to whom a market authorisation is issued the 'sponsor'. The sponsor has special obligations under the Bill, including respons bilities relating to post-market surveillance and monitoring.

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 activities. Manufacturing and exporting a natural health product in the course of business are controlled activities, as is carrying on a pharmacy business.

Individuals who engage in controlled activities without authorisation are subject to a range of penalties, including fines and imprisonment.

The Bill authorises various persons to engage in controlled activities (for example, health practitioners prescribing prescription medicines), following an application to the regulator for a licence or permit and successful evaluation. The Bill imposes obligations on licence and permit holders and those who work for them ('responsible persons').

While not a controlled activity, the Bill allows the regulator to impose restrictions on advertising activities related to therapeutic products.

The regulator and regulatory matters

The Bill establishes a new therapeutic products regulator ('the regulator'). The regulator will be a public servant appointed by the Chief Executive of the Ministry of Health on the basis of their relevant knowledge and expertise. The regulator will exercise their powers under the Bill independently of the Chief Executive and the Minister of Health – but may be subject to general policy directions issued by the Minister. *Part 9* of the Bill provides the regulator with a broad cost recovery power, whereby the regulator will be able to impose fees, charges and levies to fund its activities.

The regulator will be expected to work productively with other parts of the health system, including Manatū Hauora – the Ministry of Health, Te Whatu Ora – Health New Zealand, Te Aka Whai Ora – the Māori Health Authority and Pharmac. Reflecting the global nature of therapeutic product regulation, the regulator will also work cooperatively with overseas organisations and regulators in comparable jurisdictions.

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.

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

As Crown organisations are large users of therapeutic products (and manufacturers of medical devices), the Bill extends criminal liability to Crown organisations for some contraventions of the Bill. *Schedule 3* lists the Crown-enforceable offences and Crown-enforceable infringement offences. The regulator will also be able to seek an injunction against, and enter into an enforceable undertaking with, a Crown organisation. Civil penalty orders cannot be made against a Crown organisation.

The Bill requires the regulator follow due process in making certain decisions and establishes an internal review mechanism for these 'reviewable decisions' (*Schedule 2*). A requirement for the regulator to publish a regulatory strategy will provide additional transparency to regulated parties and the public.

The Minister will be able to prohibit the import, manufacture, supply, export, prescription of, administration, use on a patient, or acquisition for the purposes of carrying on a supply chain activity outright where the product 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.

Finally, the Bill establishes a therapeutic product register. This will be a publicly available record of therapeutic products that hold (or held) a market authorisation, products where an application for an authorisation has been submitted and products for which an authorisation has been refused. The register will also include details on all license and permits: for example, who is licenced to manufacture a particular active pharmaceutical ingredient.

Effects on other legislation and statutory regimes

Part 11 of the Bill will repeal most provisions of the current Medicines Act, except those relating to pharmacy ownership requirements. Regulations made under the Medicines Act will be revoked by the Bill on commencement. The Bill is not intended to 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 Bill also amends the Human Tissue Act 2008 and Human Assisted Reproductive Technologies Act 2004 to clarify the relationship between these regimes. These amendments do not weaken the fundamental ethical principles underpinning the collection and use of these tissues.

Minor amendments will be made to statutory regimes that interface with the Bill, including the Hazardous Substances and New Organisms Act 1996 and the Food Act 2014.

Schedule 1 *sets* out transitional, savings and related provisions. Products which are currently consented under the Medicines Act will receive a market authorisation under this Bill. Products that did not previously require a consent under the Medicines Act before they could be supplied in New Zealand (e.g., medical devices and natural health products) will have 2-5 years to seek a market authorisation. Transitional periods will start from the commencement of the Bill.

Those who are lawfully engaged in activities that are regulated under this Bill as controlled activities (e.g., clinical trials) at the time of its enactment will have a period of time in which to apply for a new licence or permit to continue to undertake those activities.

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?	NO

Relevant international treaties

2.2. Does this Bill seek to give effect to New Zealand action in relation to an international treaty?	YES
s9(2)(h)	

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
s9(2)(h)	

Commented [RRG11]: s9(2)(h)

Regulatory impact analysis

2.3. Were any regulatory impact statements provided to inform the policy decisions that led to this Bill?	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), 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: Regulating natural health products, 17 March 2022 Accessible at https://www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime Some content is withheld to protect the confidentiality of advice tendered by Ministers of the Crown and officials. [Pharmacy ownership, supplementary RIS links to be included.]	

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 considers that the RIS meets 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 considers that the RIS meets the quality assurance criteria.

The Ministry of Health and the Regulatory Quality Team at the Treasury has 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 meets 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 has reviewed the Impact Statement titled "Pharmacy ownership and licensing", 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 QA panel has 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.

[Include comment from PARC on supplementary RIS]

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 policy position long-term 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 until it is managed as an endemic or seasonal illness. Continuing with the status quo will not jeopardise the ongoing provision of safe and effective medicines and other therapeutic products.

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 statement 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.	

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 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.	

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?
s9(2)(h)

Commented [RBG21]: s9(2)(h)

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. The Ministry has engaged with Māori clinicians and health providers on the Bill. Specific regard has been had to advice received from Te Aka Whai Ora – the Māori Health Authority and Te Arawhiti on the Bill. Advice on proposals to reflect the principles of Te Tiriti o Waitangi (Te Tiriti) in the Bill was jointly developed between the Ministry and Te Aka Whai Ora, with external advice provided by Te Arawhiti and the Treaty Provisions Oversight Group. Te Puni Kōkiri was consulted on the Bill. 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 related to decision making principles, review panels, consultation requirements and the functions of the regulator were drafted to be consistent with these principles. The relationship of the Bill to rongoā Māori was explored through a series of wānanga and hui involving a representative from Te Kāhui Rongoā, a peak governance group for rongoā practitioners, and officials from the interim Māori Health Authority and wider Ministry. Options for regulating rongoā under the Bill were jointly developed by the Ministry and Te Aka Whai Ora. The Bill does not currently contain any specific references to rongoā.

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 has been sent to the Ministry of Justice in order for them to prepare advice on consistency with the New Zealand Bill of Rights Act 1990. Advice provided to the Attorney-General by the Ministry of Justice is generally expected to be made available on the Ministry of Justice's website upon introduction of a Bill. Such advice will be accessible on the Ministry's website at http://www.justice.govt.nz/policy/constitutional-law-and-human-rights/human-rights/bill-of-rights/ If the Attorney-General determines the Bill to be inconsistent with the New Zealand Bill of Rights Act, a section 7 report will be published on the Ministry's website and tabled in the House.

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, clauses 290, 328 and 420) 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 related 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**
Yes. The Bill contains several clauses (for example, clauses 294, 332 and 426 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. The Privacy Commissioner has raised some initial concerns about the breadth of these overrides and will work with officials to address these.	

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 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.	

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 Service and Te Whatu Ora).	

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 LDAC 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 attr bute the state of mind of senior managers, workers or agents to a corporate entity. Contraventions committed by a body corporate can be attr buted 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 (ie., 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.

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 issue injunctions against Crown organisations and Crown employees.

The Bill at clause 339 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 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 is operationalised via a system of market authorisations, licences, permits and standing permissions in the Bill. 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. However, these interests are not commonly protected or recognised by law. For example, health practitioners are subject to requirements on how and where they can practice. The Medicines Act currently restricts a range of similar activities for medicines and pharmacy business. 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. The Bill provides that regulations made that restrict these practices must be necessary and proportionate.	

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 16(3) provides a power for the Minister to define a product as a therapeutic product – or to and exemption power in the Act.	

4.8. Does this Bill create or amend any other powers to make delegated legislation?	YES
Clause 458 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?	NO

From: BROWNLEE, Victoria (ECO) <Victoria.Brownlee@mfat.govt.nz>
Sent: Friday, 7 October 2022 3:37 pm
To: 'Tim.Vines@health.govt.nz' <Tim.Vines@health.govt.nz>
Subject: RE: [IN-CONFIDENCE] Request from the Ministry of Health for rapid feedback on the draft Therapeutic Products Bill - due COB 7 October

Kia ora Tim,

Thanks again for giving MFAT the opportunity to provide feedback on the draft Therapeutic Products Bill.

A marked-up version of the Bill with our comments is attached. For context, I shared the draft with the following divisions (noting which specific aspects of the Bill they are interested in, where possible):

- **Economic (ECO).** Our main interest is in ensuring that the Bill resolves issues with exporting NHPs. s6(a) so we support the new legislation.

- s9(2)(h)

- **Trade Policy & Negotiations (TPND).** TPND are keen to ensure that the Bill is consistent with the WTO Agreement on Technical Barriers to Trade.

- **Development, People and Planet (DEVPP).** For DEVPP, NZ's support to Polynesian and other Pacific countries is front of mind. In particular, during the COVID-19 pandemic Aotearoa New Zealand has been supplying COVID-19 vaccines, medical supplies to the six Polynesian countries and Fiji and soon we will supply the Cook Islands, Niue and Tokelau with COVID-19 antivirals.

- **Australia (AUS).** As Medsafe and Australia's Therapeutic Products Agency (TPA) cooperate closely on medicines, AUS wants to ensure a revision of our legislation shouldn't negatively affect Australia or our relationship with Australia.

- **Trade Policy, Engagement and Implementation (TPEI) –** no comments.

Please let me know if you have any questions, or if there are any points you'd like us to clarify. I hope you find our feedback useful.

Ngā mihi,

Victoria

Victoria Brownlee (she/her)

Policy Officer
Trade Recovery Unit - Economic Division
New Zealand Ministry of Foreign Affairs & Trade | Manatū Aorere

[Document ID]

s9(2)(a) **E** victoria.brownlee@mfat.govt.nz

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