MANATŪ HAUORA
MINISTRY OF HEALTH

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15 February 2023

Tracy Livingston

By email: fyi-request-21576-be234fbc@requests.fyi.org.nz
Ref: H2023019554

Tēnā koe Tracy

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Hauora (the Ministry of Health) on 18 January 2023 for information regarding the Therapeutic Products Bill (the Bill). Please find a response to each part of your request below.

1. *With whom has the Ministry of Health engaged regarding writing of the Therapeutic Products Bill?*

The Bill has been through a long period of extensive consultation and development. There was considerable consultation and engagement on the Natural Health and Supplementary Products Bill, which lapsed in 2017. This Bill builds on the significant work done then, taking into consideration previous contentious issues.

In 2018, an exposure draft of the Bill, which did not include natural health products, was released for public consultation. All these consultations sessions were open to the public. Background to the public consultation, including the consultation document and key themes from submissions, can be found at: www.health.govt.nz/publication/therapeutic-products-regulatory-scheme-consultation.

In 2019, there were open forums held for sectors relevant to the Bill, and Māori groups connected to those sectors were specifically invited to join. This information is outlined in Document 1 of Appendix 1, which shows the schedule for each forum.

On 30 November 2022, Minister Henare announced a new rongoā workstream alongside the Bill to assess the interface between rongoā Māori and the Bill. This mahi has included targeted engagement with key stakeholders, Māori partners, and expert groups. Minister Henare's press release announcing the new workstream can be found at this link https://www.beehive.govt.nz/release/new-rongo%C4%81-workstream-announced-alongside-therapeutic-products-bill.

Manatū Hauora also engaged with a range of stakeholders in 2022 on different aspects of the Bill including natural health products, rongoā and medical technology. This includes:

- Consultation with the Natural Health Product sector on 1 and 3 November 2022; and
- Consultation about rongoā Māori with a range of stakeholders (including Te Kāhui Rongoā and Interim Māori Health Authority) on 31 May, 2, 7 and 30 June 2022.

Public consultation on the Bill is ongoing. The Bill is currently with Parliament's Health Select Committee. The Committee has called for written submissions from the public, and can also invite individuals to present to the Committee. If you have feedback about the Bill, you can make a submission by visiting www.parliament.nz/en/pb/bills-and-laws/bills-proposed-laws/document/BILL_130084/therapeutic-products-bill. Submissions on the Bill close 11:59pm, Sunday 5 March 2023.

2. *Please include all reports, requests, emails and lobby group engagements that have facilitated the decision making and writing of this bill including minutes of all meetings of pharmaceutical companies with Andrew Little that discuss this Bill*

Due to the broad scope of this part of your request, the Ministry contacted you pursuant to section 18B of the Act on 1 February 2023, to ask you to refine this part of request. You were informed that your request may be refused under section 18(f) of the Act as the information requested could not be made available without substantial collation or research. It was suggested that you refine your request to formal correspondence only, from 2021 to present.

On 1 February 2023 you responded that you would like to refine your request to "*Informal and formal correspondence, including text messages, from 2021 to present*". The use of the word "informal" has broadened the scope of your request to one that would require substantial collation and research. For this reason, I am refusing your request pursuant to section 18(f) of the Act.

However, we have identified some documents that may be relevant to your request. Documents 2 to 6 were identified in scope of this part of your request and are outlined in the table in Appendix 1 of this letter, with copies enclosed. Where information is withheld under section 9 of the Act, I have considered the countervailing public interest in releasing information and consider that it does not outweigh the need to withhold at this time.

In addition, I have considered your revised request for text messages and can advise that no text messages related to industry or lobby engagements that facilitated the decision making or writing of the Bill are held by the Ministry.

Finally, for the Hon Andrew Little MP's publicly released meeting list, please visit the Beehive's website at:
www.beehive.govt.nz/search?f%5B0%5D=content_type_facet%3Aministerial_diary&f%5B1%5D=ministers%3A6473&f%5B2%5D=government_facet%3A6455.

If you would like to clarify your request by asking for specific documents or information, please do so. This would assist the Ministry in identifying and providing further documentation that may be relevant to you.

3. *Who is the actual author of the bill itself?*

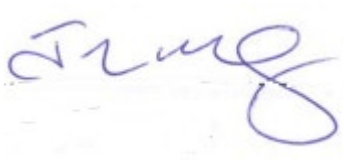
There is no single author of the Bill. Legislative drafters at the Parliamentary Counsel Office | Te Tari Tohutohu Pāremata are responsible for drafting legislation, based on drafting instructions prepared by the Ministry.

Further information about the legislative process is available at: https://policy-to-law.pco.govt.nz.

I trust this information fulfils your request. Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā



John McGrath
Director, Priority Projects
Strategy, Policy and Legislation | Te Pou Rautaki

Appendix 1: List of documents for release

#	Date	Document details	Decision on release
1	13 February 2019	Email - Consultation schedule for the draft Therapeutic Products Bill	Some information withheld under section 9(2)(a) of the Act, to protect the privacy of natural persons.
2	1 July 2021	Aide-Mémoire - Meeting with CEO of Medicines New Zealand (HR20211531)	
3	7 October 2021	Aide-Mémoire - Meeting with Minister Wood to discuss COVID-19 technology and supporting New Zealand innovation (HR20212199)	
4	9 November 2021	Aide-Mémoire - Meeting with representatives from Johnson & Johnson on value-based healthcare (HR20212450)	
5	8 August 2022	Event briefing and speech for the Medicines New Zealand Annual Stakeholder Dinner 2022 (HR20221271)	
6	15 November 2022	Aide-Mémoire - Meeting with the Medical Technology Association of New Zealand (HR2022016300)	

Document 1

Document Profile

Therapeutics Domestic Regulatory Scheme

Status:	Final
Date:	13/02/2019
Title:	Consultation schedule for the draft Therapeutic Products Bill
Author:	Hannah Adams
Document Type:	Email
Summary:	
Knowledge Content:	Med

Drawer:	2. Stakeholder Engagement and Communications
Folder:	2. Stakeholder Engagement\Correspondence\2019
File Location:	
Unit:	Ministry of Health System Strategy and Policy Regulatory Policy\Safety and Access
Maintainer(s):	Alison Cossar Andi Shirtcliffe Andrea Eng Jane Hubbard Michael Haynes Patricia Farrelly Saerom Shin Sue Scott Hannah Adams Strategy and Policy System Strategy and Policy Michael Roberts

Hi Megan and Fiona

It was nice to meet with you this morning.

Here is our schedule for the sector forums on the draft Therapeutic Products Bill. We have also just started discussion whether we should hold a general forum in Christchurch, as we aren't holding any forums in the south island.

Sector	Date	Location
Medicines	Afternoon, Monday 18 March	Auckland
Medical devices	Morning, Tuesday 19 March	Auckland
Cell & Tissue	Afternoon, Tuesday 19 March	Auckland
Research	Morning, Wednesday 20 March	Auckland
Pharmacy	Morning, Thursday 21 March (TBC – this is a change from the originally proposed time of morning Friday 22 March)	Wellington
General / Consumer	Afternoon, Thursday 21 March	Wellington
Health Practitioners	Afternoon, Friday 22 March	Wellington
Research	TBC	Due to the low number of registrations we intend to

		video conference with those stakeholders

I have added Fiona to the list of attendees for the medical device forum on 19 March. If you decide you would like additional people to attend that forum or would like to attend another forum please let me know.

Kind regards,
Hannah

Hannah Adams
Senior Policy Analyst (Part time: Monday - Wednesday 9.30am to 2.30pm & Thursday 9.30am to 6pm)
Regulatory Policy
System Strategy and Policy
Ministry of Health
DDI: S9(2)(a)
Fax: 04 4692191

http://www.health.govt.nz
mailto:Hannah_Adams@moh.govt.nz

Document 2

MINISTRY OF HEALTH
MANATŪ HAUORA

Aide-Mémoire

Meeting with CEO of Medicines New Zealand

Date due to MO	1 July 2021	**Action required by:**	N/A
Security level	IN CONFIDENCE	**Health Report number:**	20211531
To:	Hon Andrew Little, Minister of Health		

Contact for telephone discussion

Name	Position	Telephone
Fiona Ryan	Manager Therapeutics, System Strategy and Policy	S9(2)(a)

Document 2

Aide-Mémoire

Meeting with CEO of Medicines New Zealand

Date due	1 July 2021		
To	Hon Andrew Little, Minister of Health		
Security level	IN CONFIDENCE	**Health report number:**	20211531

Details of meeting
Friday 2 July 2021
2:30 – 3:00 pm, Minister's office, 6.1 EW

Purpose of meeting
Meeting with Dr Graeme Jarvis, CEO of Medicines New Zealand

Comment

- This is your first meeting with the CEO of Medicines New Zealand, the peak body for the pharmaceutical industry in New Zealand.
- Hon Chris Hipkins, as previous Minister of Health, spoke at the organisation's annual dinner in July 2020.
- This aide-mémoire discloses all relevant information.

Fiona Ryan
Manager Therapeutics
System Strategy and Policy

Document 2

Meeting notes

Medicines New Zealand

The organisation

- Medicines New Zealand (MNZ) is the industry association representing companies involved in the research, development, import and manufacture of medicines.
- It advocates to improve access to what it terms 'modern medicines' for New Zealand patients.
- This year MNZ gained full membership of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), which is based in Geneva. To be accepted as a member, MNZ had to demonstrate compliance with IFPMA's code of ethics and values.
- One of MNZ's workstreams is to apply a code of practice to ensure high standards of ethical and responsible promotion of prescription medicines in New Zealand, and wherever possible to exceed those required by law. Compliance with this code is a condition of membership. (You will soon be briefed on direct-to-consumer advertising of prescription medicines, as part of the work on the Therapeutic Products Bill.)

Graeme Jarvis

- Dr Jarvis has been CEO of Medicines New Zealand for more than six years.
- His career has included managing research and development in the primary production and food sectors, and as a sector manager with New Zealand Trade and Enterprise.
- He has a PhD in microbial physiology and biotechnology, and an MBA in strategy and marketing.

PHARMAC

Review status

- The Government has established an independent review of PHARMAC, which will report back in December. It will focus on two main questions:
    - how well PHARMAC performs against its current objectives, and whether and how its performance against these could be improved
    - whether PHARMAC's current objectives maximise its potential to improve health outcomes for all New Zealanders, and whether and how these objectives should be changed.
- Key considerations for the review are:
    - the timeliness of PHARMAC's decision making (in particular for new medicines)
    - the transparency and accessibility of decision-making processes
    - equity, including access to medicines and devices for Māori and Pacific peoples.

Medicines New Zealand position

- MNZ has publicly supported the independent review of PHARMAC.
- Along with some other stakeholders, it has stated a preference for a separate appropriation for PHARMAC and an increase to the combined pharmaceutical budget.
- It has complimented the Government on its swift moves to fund COVID-19 health measures, but has contrasted this with the existing procurement system, which MNZ calls "not fit for purpose".
- The meeting would be a good opportunity to hear what changes MNZ sees as necessary to obtain a national medicines procurement system that optimally serves the needs of both patients and the country.

Medicines funding

- The size and fixed nature of the combined pharmaceutical budget (CPB) is out of scope for the review. This is because the Government must decide whether an increase in pharmaceutical spend has priority over other investments in health, or other areas of potential spending.
- The CPB is informed by PHARMAC's projections for population demand, demographics, supply-side pressures and negotiation with DHBs. PHARMAC has succeeded in expanding access to medicines, and the range of medicines available to New Zealanders, within a fixed budget.
- The CPB has increased by 23% in the past four years (to $1.119 billion, excluding one-off COVID-19 costs).
- In Budget 2021 a further $200 million was allocated to the CPB over the next four years.

International comparisons

- Health sector groups sometimes compare New Zealand's pharmaceutical spend with that of other OECD countries, as a percentage of total healthcare costs or of GDP. Comparisons can be misleading because of different countries' circumstances, and missing data.
- The proportion of total healthcare spending that goes on pharmaceuticals is affected by what is included in total healthcare spending. This varies between countries.
- PHARMAC negotiates some of the lowest pharmaceutical prices in the world, reducing overall expenditure in New Zealand.
- Institutional and funding arrangements differ. For example, publicly-funded medicines in New Zealand are free apart from a small co-payment on prescriptions. Medicines available in some other countries require significant payments from patients.
- The information provided by PHARMAC to the OECD does not include medicines dispensed in hospitals or outpatient settings, or medicines purchased over the counter. The OECD has stopped including New Zealand data in some of its reporting, for reasons unknown.

Access and equity

- One of PHARMAC's strategic priorities is 'Equitable access and use'.
- One deliverable is "develop and implement medicine access action plans for up to two priority clinical conditions for Māori and Pacific peoples". Another is work on enabling systematic generation of medicine access data insights for priority conditions for Māori, including dissemination of that information in the sector.

Medsafe and Medicines New Zealand

Fees review

- Medsafe has reviewed its fees and identified some areas where costs are not being fully recovered. Some proposed fee changes will affect MNZ members, with some significant increases in targeted areas.
- MNZ has been consulted on the proposed fee changes. It and some of its members provided feedback on the proposals. Medsafe is reviewing the submissions and testing the alternative proposals submitted by MNZ.
- Overall, MNZ was positive about the review, and Medsafe appreciates its considered approach. A summary of the final proposals will be available shortly.

Collaboration and engagement

- MNZ and Medsafe are beginning a new collaboration and engagement process, with the first meeting next week.
- This approach was initiated by MNZ, and Medsafe is pleased to be involved. The meeting is intended to explore areas where MNZ and Medsafe can work together on issues of mutual interest without compromising the position of each party, and determine a framework for future engagement.
- Some small, defined projects have been identified to test the framework before moving on to larger issues. An example is collaborating to improve application forms. This will ensure that the pharmaceutical industry provides the required correct information, so Medsafe can process applications efficiently. This is to the benefit of both parties.

COVID-19 vaccine approval

- COVID-19 vaccine approvals continue to be assessed by Medsafe. The rolling nature of the applications seems to be working well, with positive feedback from pharmaceutical industry.

New regulatory scheme for therapeutic products

Developing a new regulatory scheme

- Replacing the Medicines Act 1981 is long overdue. A whole new regulatory scheme for therapeutic products (including medicines and medical devices) is being developed, and the new Therapeutic Products Bill is at the heart of this work.
- The draft Bill was consulted on in 2019. The need to respond to the COVID-19 pandemic during 2020 has delayed progress, however work has gathered pace during 2021.

- MNZ made a submission, along with over 440 others. Stakeholders — including MNZ — broadly support the direction indicated in the exposure draft.
- The Ministry's focus has been on the key issues that will deliver a modern, fit-for-purpose scheme that proportionately regulates the full range of therapeutic products. The Bill will be part of a wider system for delivery of safe, effective, high-quality therapeutic products to New Zealanders.
- A revised draft Therapeutic Products Bill will be introduced to the House as soon as possible, and there will be further opportunity for stakeholder input when it is considered by a select committee. [Officials have advised you we are working to have the Bill ready for introduction in early 2022.]
- Much of the fine detail of the new regulatory scheme will be in regulations and other subordinate instruments, and again these will be developed in full consultation with interested parties.

MNZ's interest

- MNZ provided a thorough and considered submission on the Bill. This effort is appreciated, and its points are being considered carefully. Officials will continue to meet MNZ regularly and are working through the issues raised in its submission on the Bill.
- MNZ supports the general design of the new regulatory scheme for therapeutic products. Along with other stakeholders, MNZ is interested in the detail that will be contained in subordinate instruments.
- The Bill provides for the purpose and principles of the regime, and sets parameters such as risk proportionality, cost-effectiveness and impartiality. The future regime will be consistent with international best practice.

Medicine supply chain

Disruptions

- The COVID-19 pandemic is causing significant disruption to global supply chains, including for medicines. Ingredient supply, product manufacturing and shipping are all affected.
- PHARMAC and Medsafe continue to work closely in playing key roles in securing New Zealand's medicine supply in a global market disrupted by the pandemic.
- MNZ's member companies have been at the forefront of responding to these challenges. These companies include those supplying vaccines and other critical medicines. We appreciate the work MNZ and its members are continuing to do in very challenging times.
- Dr Jarvis will have valuable insights into how the medicine sector is planning to manage a continued disruption to manufacture and supply.

Document 3

Aide-Mémoire

Meeting with Minister Wood to discuss COVID-19 technology and supporting New Zealand innovation

Date due to MO:	07 October 2021	**Action required by:**	07 October 2021
Security level:	IN CONFIDENCE	**Health Report number:**	HR 20212199
To:	Minister Verrall, Associate Minister of Health		
Copy to:	Minister Little, Minister of Health Minister Hipkins, Minister for COVID-19 Response		

Contact for telephone discussion

Name	Position	Telephone
Fiona Ryan	Manager Therapeutics, System Strategy and Policy	S9(2)(a) [redacted]
Caroline Flora	Associate Deputy Director-General, System Strategy and Policy	

Document 3

Aide-Mémoire

Meeting with Minister Wood to discuss COVID-19 technology and supporting New Zealand innovation

Date due:	07 October 201
To:	Minister Verrall, Associate Minister of Health
Security level:	IN CONFIDENCE **Health Report number:** HR 20212199

Details of meeting:
Thursday, 7 October 2021
09:30am
Zoom meeting – your office will provide the relevant Zoom link

Purpose of meeting:
To discuss with Minister Wood a briefing provided to you in your role as Associate Minister of Research, Science and Innovation that sets out alleged regulatory and other barriers to the adoption of new health technologies, in particular those funded via the COVID-19 Innovation Acceleration Fund.

Comment:

Background

- The Ministry of Business, Innovation and Employment (MBIE) has briefed you in your capacity as Associate Minister of Research, Science and Innovation on regulatory and other barriers to the adoption of new health technologies, in particular those funded via the COVID-19 Innovation Acceleration Fund (CIAF).
- You will be discussing this briefing and the issues raised in it with Minister Wood on the morning of Thursday 7 October 2021.
- The issues raised are also relevant in your role as Associate Minister of Health and the Ministry of Health has prepared talking-points on the health-related aspects of the briefing, including the regulation of therapeutic products. Matters related to the governance of MIQ and operational MIQ matters should be addressed by MBIE.
- Ministry of Health officials will attend this meeting and will be available to provide further advice.
- This aide-mémoire discloses all relevant information.

Fiona Ryan
Manager, Therapeutics
System Strategy and Policy Directorate

Talking points on health-related aspects of the briefing

Regulation as a 'barrier' to innovation & reforms to therapeutics regulation

Risk-proportionate regulation can support innovation

- Due to the risks to patient safety associated with therapeutic products (including PPE), it is legitimate that their approval be subject to appropriate oversight and control.
- Indeed, confidence in a product's safety – as attested to via a regulator's approval – is likely to support innovation by driving the uptake of new health technologies. This is because the uptake of new health technologies often depends on the willingness of clinicians, facility administrators and patients to accept the use of new technologies.
- As such, fit-for purpose regulation supports innovation but provides appropriate guardrails to ensure that important values, such as patient safety and cost-effectives, are protected.

This applies equally during the COVID-19 pandemic

- Our response to COVID-19 has required us to be dynamic and open to novel solutions.
- However, even in these circumstances, regulation plays an important role in securing trust and acceptance for innovation. For example, contact tracing must be undertaken in a privacy-compliant manner or it risks undermining user-acceptance or even the loss of foundational technologies (eg, Apple and Google's Bluetooth functionality).
- Privacy and product safety regulation will therefore remain important whether an innovation is being applied in MIQ or a workplace.

Our reforms to the regulation of therapeutic products will support innovation

- Although the current *Medicines Act 1981* (the Medicines Act) has worked well enough during the current COVID-19 outbreak, we are aware of its shortcomings.
- As you are aware, the Ministry of Health is leading the development of a new Therapeutic Products Bill, that will replace the current Medicines Act with a modern regulatory regime.
- An explicit policy objective for the new Bill is that it supports New Zealand's trade and economic objectives. This includes supporting local innovation and the adoption of technology in New Zealand that can improve productivity and health outcomes.
- The new regime will support local innovation by improving the acceptance and recognition of international standards and the decisions of respected product regulators. It will also embed a risk-proportionate approach to product approval.

While options exist to support New Zealand innovators secure local approval, our regulatory processes must be 'applicant neutral'

- Both our existing and new therapeutic regulatory regime will apply equally to local and international applicants.
- While there may be good policy reasons to support New Zealand applicants in regulatory and procurement decisions, both regimes ought to remain neutral with regards to the

nationality of an applicant. This ensures fairness in decision-making and compliance with our international trade obligations relating to non-discrimination.

- Funders of health and medical research could consider how funding rules take into account the costs of seeking product approval and whether support should extend to engaging individuals with knowledge of product approval pathways as part of a research team.

Specific medical device issues

A number of CIAF-funded health technologies are 'medical devices' for the purpose of the Medicines Act but others are not likely to be captured

- I have been advised that COVID-19 testing and diagnostic devices, medical equipment to treat COVID-19, health monitoring equipment and PPE would fall within the definition of 'medical devices' under the current and future therapeutic products regulatory regime.
- However, other technologies that do not have a 'therapeutic purpose', such as contact tracing or software to coordinate health services are unlikely to be regulated under the current and future framework.

A lack of regulation can hinder innovation, just as much as inappropriate regulation

- As highlighted in the briefing, a lack of regulation has made the development and implementation of new technologies difficult.
- Our current regime is lacking in several areas. For example, the Medicines Act does not currently set out any product standards for medical devices to meet before they enter the New Zealand market. Nor does it support the regulator to rely on the decisions of respected international counterparts.
- The new Therapeutic Products Bill will introduce pre-market regulatory oversight of medical devices to ensure product safety including setting product standards commensurate with risk profiles of various types of medical devices. This will provide applicants with more certainty.
- The Bill will also enable various market authorisation pathways to be designed for exceptional circumstances – such as pandemics – to allow timely adoption and deployment of health technologies while achieving product safety and quality.

Additional matters

The slow adoption of new health technologies is a globally recognised issue

- I understand the frustration of CIAF-applicants. The slow adoption of technology and improved clinical practices in the health system is an international phenomenon.
- The barriers to adoption include the funding gap between 'benchtop and bedside', risk-adverse regulatory and workplace cultures, liability fears, clinician autonomy, lack of incentives to adopt new tools and, to varying extents, government regulation.
- However, our response to COVID-19 has shown us that we can respond quickly without compromising patient safety.
- The wider health reforms agreed to by Government seek to build on the lessons of our COVID-19 response, as will decisions around the future therapeutics regulatory regime.

Document 4

MINISTRY OF HEALTH
MANATŪ HAUORA

Aide-Mémoire

Meeting with representatives from Johnson & Johnson on value-based healthcare

Date due to MO:	9 November 2021	**Action required by:**	10 November 2021
Security level:	IN CONFIDENCE	**Health Report number:**	HR20212450
To:	Hon Dr Ayesha Verrall, Associate Minister of Health		

Contact for telephone discussion

Name	Position	Telephone
Fiona Ryan	Manager Therapeutics, System Strategy and Policy	S9(2)(a) [redacted]
Caroline Flora	Associate Deputy Director-General, System Strategy and Policy	

Document 4

Aide-Mémoire

Meeting with representatives from Johnson & Johnson on value-based healthcare

Date due:	9 November 2021
To:	Hon Dr Ayesha Verrall, Associate Minister of Health
Security level:	IN CONFIDENCE **Health Report number:** HR20212450
Details of meeting:	10 November 2021 4:00pm – 4:30pm
Purpose of meeting/ proposal:	Representatives from Johnson & Johnson New Zealand wish to meet with you to discuss the role of value-based health care in improving health outcomes and reducing the total cost of care. The meeting is also likely to discuss the independent review of Pharmac and Pharmac's review process for medicines and medical devices.

Comment:	• The Johnson & Johnson representatives attending this meeting are:
	  ○ Sarah Najdek, Country Manager & Managing Director for New Zealand
	  ○ Carmel Murphy, Government Affairs & Policy Manager
	• A biography of the two attendees is included at **Attachment 1**.
	• The Pharmac review is still ongoing. The independent review panel provided its Interim Report to the Minister of Health on 16 September 2021 and it is under consideration by the Government.
	• Talking points are included at the end of the aide-mémoire.
	• This aide-mémoire discloses all relevant information.

Caroline Flora
Associate Deputy Director-General
System Strategy and Policy

Background

Johnson & Johnson and Janssen

- Founded in the USA 135 years ago, Johnson & Johnson is one of the world's largest manufacturers of medicines, medical devices and consumer healthcare products.
- Its New Zealand branch was established in 1945 and operates as three divisions:

Company	Areas of focus
Johnson & Johnson Pacific	• over-the-counter products like Johnson's Baby, Band-Aid, Aveeno, Codral and Nicorette • innovations in areas such as smoking cessation and sun protection
Janssen Pharmaceutical Companies of Johnson & Johnson	• pharmaceuticals to prevent, treat and cure diseases including prostate cancer, blood cancers, schizophrenia, inflammatory bowel disease and psoriasis • a subsidiary of Johnson & Johnson. Its Covid-19 vaccine was provisionally approved in New Zealand in July 2021
Johnson & Johnson Medical Pty Ltd	• innovative technologies, tools and artificial joints, biomaterials used in the treatment of many pervasive conditions from cancer to cardiovascular disease and trauma surgery • a member of New Zealand Health IT (NZHIT) and Medical Technology Association of New Zealand (MTANZ)

- Johnson & Johnson has also undertaken several projects and programmes to address equity for Māori and Pacific, including:
    - Mauri Ora Social Innovation: a partnership with Te Rau Ora, Manawanui and Waikato DHB to support Māori with schizophrenia.
    - Upside Life on the Up Youth Mentoring Partnership: a partnership with Upside to support young people with adverse childhood experiences to improve education attainment, physical and mental health.
    - Salvation Army Positive Lifestyle Programme for Māori Women: a long-standing partnership with The Salvation Army to increase the physical, emotional, spiritual and family health of vulnerable Māori women and their strength as nurturers and leaders within their whānau.
- Johnson & Johnson have also invested in research and workforce initiatives supporting Māori through scholarships with the Royal Australian College of Surgeons.

Value-based healthcare

- Value-based care (VBC) is about improving the value of healthcare spending by improving the outcomes that matter most to patients. It seeks to address the rising costs of healthcare globally, due to people living longer, the rise of chronic diseases, wage rises and the increase in other costs associated with the design and delivery of healthcare.
- VBC takes a patient-centred and holistic approach to care helping patients recover from illnesses and injuries more quickly and avoid chronic disease in the first place.
- VBC differs from a fee-for-service or capitated approach and is commonly understood as centring on six 'elements'.
    - Organise care delivery around the medical conditions of patients or segments of the population.
    - Measure outcomes and cost for every patient.
    - Align reimbursement with value.
    - Integrate systems to organise regional delivery of care around matching the correct provider, treatment, and setting.
    - Geography of care: national centres of excellence to provide care for exceedingly complex patients.
    - Use an information technology system to support the value-based approach.[1]
- VBC is supported by value-based procurement, which focuses on value, is outcomes-based, integrated, focused on total cost, prospective and strategic.
- Key stakeholders in the pharmaceutical and medical device sector support VBC models. The Medical Technology Association of New Zealand (MTANZ) support a value-based approach to medical device procurement.

Pharmac's role in providing affordable, equitable access to medicines and medical devices

- Pharmac is the Crown entity responsible for making decisions about what pharmaceuticals are publicly funded within a fixed budget and negotiating the best value for money for them on the international market.
- Since it was established, Pharmac's role has widened to also include medical devices, vaccines, haemophilia products, cancer medicines and hospital medicines.

The independent review of Pharmac

- As a large supplier of therapeutic products, Johnson and Johnson and its subsidiaries have an interest in the current independent review of Pharmac.
- On 2 March 2021, the Government announced an independent review into Pharmac to ensure that the public can have confidence in it and its role in the wider health and disability system. The review is being undertaken by an expert review Committee chaired by Sue Chetwin.
- The review focuses on two areas:

[1] Christer Mjåset et al, 'Value-Based Health Care in Four Different Health Care Systems' *New England Journal of Medicine Catalyst* (November 2010) DOI: 10.1056/CAT.20.0530.

    - How well Pharmac performs against its current objectives and whether and how its performance against these could be improved.
    - Whether Pharmac's current objectives maximise its potential to improve health outcomes for all New Zealanders as part of the wider health system, and whether and how these objectives should be changed.
- Note: VBC and value-based procurement are not explicitly within the terms of reference for the review.
- Submissions to inform the review closed on Friday 16 July. As the review is independent of the Ministry, we do not have access to the submissions, including any possible submission from Johnson and Johnson.
- An independent review of Pharmac is currently underway, and Minister Little intends to take the Pharmac review interim report to Cabinet before the end of 2021. Pending the outcome of Cabinet consideration, Minister Little has indicated he intends to release the interim report publicly.
- The Ministry and Pharmac have each now received copies of the interim report in confidence for comment following the Minister's approval (noting the interim report is subject to any necessary minor, technical and editing changes prior to public release).

New regulatory scheme for therapeutic products

- The Ministry of Health is continuing to progress the Therapeutic Products Bill. It will replace the Medicines Act 1981 which is outdated and has not kept pace with changes in health technology.
- The Therapeutic Products Bill will provide assurance of the safety, quality and efficacy of therapeutic products which include medicines and medical devices. It will deliver a modern, fit-for-purpose scheme that proportionately regulates the full range of new and emerging medical technologies.
- The Bill will be introduced as soon as possible and there will be opportunities for submissions as part of the Select Committee process.
- Public consultation on an exposure draft of the Bill took place between December 2018 and April 2019, and MTANZ provided a submission on the draft Bill.

Proposed talking points

- I would be interested in how you see value-based healthcare playing a role in our health system reforms
- The Government is placing equity and Te Tiriti at the centre of the reforms. I would be keen to hear your suggestions for how value-based healthcare can take account of equity?
- Has COVID-19 changed the way your company and others are approaching the issue of value-based healthcare?
- How do you see data and digital technologies as an enabler or barrier to a shift to value-based healthcare?

Attachment 1: Biography of attendees

Sarah Najdek

Sarah is General Manager and Country Director of Johnson & Johnson Medical New Zealand.
Sarah took up this role earlier this year. Her career has been mainly in Johnson & Johnson and its subsidiary companies in Australia, Singapore and New Zealand, particularly in business and market development in relation to medical devices.

Sarah is on the executive board of the Medical Technology Association of New Zealand, the peak industry body for the medical device industry in New Zealand.

Carmel Murphy

Carmel is Johnson and Johnson's government affairs & policy manager and has over twenty years' experience in the healthcare industry across Australia and New Zealand. Carmel previously worked at Pfizer, most recently as its corporate affairs manager in New Zealand.

Document 5

Event briefing

Speech for the Medicines New Zealand Annual Stakeholder Dinner 2022

Date due to MO:	8 August 2022	**Date of Event:**	24 August 2022
Security level:	IN CONFIDENCE	**Health Report number:**	20221271
To:	Hon Andrew Little, Minister of Health		

Contact for telephone discussion

Name	Position	Telephone
Fiona Ryan	Manager Therapeutics Policy, Strategy Policy and Legislation	S9(2)(a) [redacted]
Steve Waldegrave	Acting Deputy Director-General, Strategy Policy and Legislation	

Event briefing

Speech for the Medicines New Zealand Annual Stakeholder Dinner 2022

Date due:	8 August 2022		
To:	Hon Andrew Little, Minister of Health		
Security level:	IN CONFIDENCE	**Health Report number:**	202206866

About the Event

Purpose	You are attending and speaking at the Medicines New Zealand Parliamentary Dinner on 24 August 2022.	
Event/visit details	**Date:**	24 August 2022
	Time:	5.30 to 9.00 PM
	Venue:	Banquet Hall, Parliament
Attendees	100 (in person) and 50 (online) delegates from New Zealand and Australia – mostly representing member organisations of Medicines New Zealand.	
Organisation	Medicines New Zealand is an industry association representing companies engaged in the research, development, manufacture and marketing of prescription medicines. Medicines New Zealand advocates for the medicines industry.	
Ministry representatives	A number of senior Ministry officials have been invited to attend the dinner function.	
Other information	You have been invited to speak for 5-10 minutes. The panel speakers for the event are Richard Vines, Professor David Thomas, Professor Cris Print and Associate Professor Māui Hudson. The topic of their speech is **Challenges and Opportunities with Genomic Medicine**. Brief biographies of the speakers provided by Medicines New Zealand are in **Appendix Four**. You will also attend a separate event organised by the Digital Health Association (formerly Health IT) for this evening from 5:30 – 6pm. You	

	will then move to the Medicines New Zealand Dinner event. A separate event briefing will be provided for the event organised by the Digital Health Association.
Media	Media representatives will be present.

Background and details of the Parliamentary Dinner

1. Every year Medicines New Zealand (Medicines NZ) holds a Parliamentary dinner and invites leading researchers, academics, and experts to address medicines-related health issues from global and local perspectives. Members of Parliament (MPs) are invited.
2. The Parliamentary dinner is regularly attended by MPs, health specialists, researchers, pharmaceutical representatives, and representatives from industry associations such as the Medical Technology Association of New Zealand. In the past, the Chief Executives, board members and clinicians from district health boards also attended.
3. This year, the theme of the event is 'Challenges and Opportunities with Genomic Medicine'. Further information about genomic medicines is provided in 'Topical issues that may be discussed at the dinner', below.

Medicines New Zealand

4. Medicines NZ is an industry association representing companies engaged in the research, development, manufacture, and marketing of prescription medicines.
5. It advocates for the medicines industry on a range of issues including access to new and novel medicines including funding and regulatory processes for the approval of medicines, with a particular focus on timeliness and cost of obtaining approval. It compares the New Zealand medicines funding and purchasing system with other OECD countries.

Topical issues that may be discussed at the dinner

Health and Disability Reforms

6. Given the recent health and disability reforms, you are likely to receive questions on the progress of the reforms and how the new agencies; Te Aka Whai Ora – the Maori Health Authority, Te Whatu Ora – Health New Zealand and Public Health Agency are taking shape.

Budget 2022

7. Medicines NZ's post-Budget release of 19 May 2022 expressed concern that the Budget did not adequately address a necessary increase in access to medicines nor the backlog of the waiting list for publicly funded medicines. It makes international comparisons for funding medicines.

Pharmac review

8. Medicines NZ had another recent media release on 1 June 2022, which relates to the final report of the independent Pharmac review. It notes Medicines NZ's concerns of a

lack of clarity around the Government's next steps towards improving New Zealand's public medicines funding system based on the panel's recommendations. The media release is attached at **Appendix three** for your information. The Ministry recently provided you with talking points on this topic [H20220960].

Therapeutic Products Bill

9. The Therapeutic Products Bill (the Bill) will repeal and replace the Medicines Act 1981 and provide a modern, comprehensive, cost effective regulatory framework for therapeutic products (including medicines, medical devices, and biologics).

10. The Bill will provide for acceptable quality, safety and efficacy of therapeutic products across the product's lifecycle with risk-proportionate regulation. Under the Bill, therapeutic products will require an authorisation from the regulator before they can be imported and supplied in New Zealand. Usually (but not always), this authorisation will follow an evaluation by the Regulator of information supplied by product manufacturers or suppliers.

11. The new therapeutic products regulatory regime will support and enable the transformed health and disability system. It will enable service innovation, particularly in primary care and community settings. The new scheme will also align with international best practice and will be future-proofed with flexibility to ensure effective control over new technologies.

12. The Bill provides opportunities for service innovation by streamlining outdated regulatory barriers in pharmacy practice and prescribing authorities. It will also provide clear regulatory pathways for new and emerging health technologies including biologics and medical devices (e.g., genomic medicines, software as a medical device including artificial intelligence and machine learning).

Genomic medicine

13. Genomic medicine is an interdisciplinary medical specialty involving the use of genetic sequence (genome) information about an individual as part of their clinical care (e.g., for diagnostic or therapeutic decision-making) and the health outcomes and policy implications of that clinical use.

14. Genomic technology is rapidly expanding in testing, sequencing and genetic modification techniques (such as CRISPR) and may give rise to new treatments and interventions. 'Precision medicine' or 'personalised medicine' is a clinical application of genomic medicine that develops targeted prevention or treatment for a particular genomic outcome determined by diagnostic genetic testing.

Genomic medicine under the Therapeutic Products Bill

15. Products involved in genomic medicine intended for a therapeutic purpose will be regulated under the Therapeutic Products Bill through their appropriate product categories. For example, gene therapies and advanced cell-based therapies (such as CAR-T personalised cancer treatments) are defined as 'biologics' (i.e., the class of therapeutic products that are or contain human cells or tissues) and will be regulated as medicines, as their effect on the body is through a pharmacological, immunological, metabolic or genetic mode of action. Genetic testing kits used at home or in a clinical setting will likely be regulated as medical devices.

16. Under the Bill, these products will be assessed by the regulator in a risk-proportionate manner to ensure safety, quality and efficacy of genomic medicines for market authorisation. New and bespoke pathways will be designed for novel genomic medicines and their clinical trials will be regulated as a controlled activity requiring a licence or permit. The Bill will provide a clear pathway to market and clinical use for these novel therapies.

17. The therapeutic product regulatory regime for biologics will run in parallel with other regulatory approval processes, including approval through the Environmental Protection Authority for all genetically modified organisms under the Hazardous Substances and New Organisms Act 1996. Where appropriate, the product will be aligned with other regimes involving human cells and tissues and genetic information, including the Human Tissue Act 2008 and the Human Assisted Reproductive Technology Act 2004.

Attached information

18. Further event information is attached at **Appendix One**. This includes event attendees and the order of proceedings.

19. A speech is provided in **Appendix Two**.

20. Medicines New Zealand's recent media release of 19 May 2022 and 1 June 2022 is attached as **Appendix Three**

21. Biographies of panel members are provided in **Appendix Four**.

Steve Waldegrave
Acting Deputy Director-General
Strategy Policy and Legislation
Date: 03/08/2022

Appendix One: Event Notes for the Medicines New Zealand Parliamentary Dinner Function 2022

22. **Event:** Medicines New Zealand Parliamentary Dinner 2022

23. **Venue**: Banquet Hall, Parliament

24. **Contact Person**: S9(2)(a) [redacted] – Board Secretary and Office Manager, Medicines New Zealand.

25. Event Details: The Parliamentary dinner function is an annual event, organised by Medicines New Zealand. Medicines New Zealand is an industry association representing companies engaged in the research, development, manufacture and marketing of prescription medicines. Medicines New Zealand advocates for the modern medicines industry.

26. The Parliamentary dinner is regularly attended by members of Parliaments, health specialists, researchers, pharmaceutical representatives, industry associations representatives from the district health boards (Board Chairs, chief executives and clinicians) and the Medical Technology Association of New Zealand Board.

27. The theme for this year's event is 'Challenges & Opportunities with Genomic Medicine'. The panel speakers will be sharing insights into opportunities genomic medicine as innovative medicines.

28. This year, the Digital Health Association is hosting a separate event in the same evening, and you have been invited to give a speech at this event as well.

29. The draft **programme schedule** is provided below. Medicines New Zealand have advised the Ministry that a final programme including attendees cannot be provided until a week prior to the event. Therefore, the timetable below is indicative based on information the Ministry had at the time this briefing was prepared.

Time	Activity
5.00 – 5.15pm	Guests begin to arrive
5.55 pm	Guests must be seated
6.00 – 6.10pm	Minister arrives at the Dinner with Medicines NZ after attending the Digital Health Association event from 5.30 to 6.00pm.
6.10 – 6.20pm	Mihi & Karakia (5 minutes) and MC to introduce Minister
6.15 – 6.25 pm	Minister speaks (5 – 10 minutes)
6.25 – 6.30 pm	MC to introduce panel speakers
6.30 – 6.50 pm	Dinner served (20 minutes)
6.50 – 7.05 pm	Panel discussion on 'Challenges & Opportunities with Genomic Medicine'

7.05 – 7.15 pm	Dessert served
7.15 – 7.30 pm	Free flowing Q&A – MC
7.30 pm	Final speech and thanks by the Chair of Medicines NZ
7.30 pm	House of Representatives resumes (some MPs may depart)
9.30 pm	Event concludes

30. A list of invitees and attendees will be provided by Medicines New Zealand to your office a week prior to the event.

31. A draft speech is attached at **Appendix Two**.

32. Media release;

    a. We note that Medicines New Zealand issued a press release on 19 May 2022, after the release of Budget 2022. In its press release it raised concerns about medicines funding and access to publicly funded medicines including inequity issues for Māori and Pacific peoples.

    b. Medicines New Zealand also issued a press release on 1 June 2022, after the release of the final report of the independent Pharmac review. The press release praised the Government's initiative to undertake an independent review and to take on board most of the recommendations made by the panel. It also noted the lack of clarity around how the Government will act on the accepted recommendations and the rationale for rejecting some of the recommendations. The press release is attached for your information (**Appendix three**).

Appendix Two: Speech

Medicines New Zealand Parliamentary dinner speech – 24 August 2022

Mihi

Tēnā koutou katoa

Tenei te mihi ki a koutou

Kua tae mai i runga i te kaupapa o te ra

Ara ko Te Medicines NZ Annual Stakeholder Dinner

Tēnā tato katoa

Acknowledgements

It's a pleasure to join you for the Medicines New Zealand Annual Dinner 2022.

I would like to begin by acknowledging Medicines New Zealand for the valuable role you play in advocating for medical innovation in Aotearoa New Zealand.

What COVID has taught us

The last two and a half years have reiterated the urgent need for a flexible health system that can provide appropriate and timely care.

While our health system has performed admirably throughout the pandemic, and the people working within it are without a doubt world-class, we need to create a sustainable, future-proof system that works for all New Zealanders, no matter who they are or where they live.

Our new reformed health system is the first step on this journey, and our significant investment shows our commitment to achieving this vision. It will not be an overnight fix, we're trying to rebuild after years of underinvestment, but the momentum is there.

New Zealanders want to, and should be able to access health information, support, and services closer to home, and even in their own home.

While the systemic issues were not new, COVID-19 was a catalyst for a significant shift in the way the health system is used to support the health of New Zealanders.

Our health sector needed to respond to deliver critical new functionality at pace, and essentially, at a distance.

The virtual care we saw stood up during the pandemic provided more ways for people to access safe, quality, and convenient services.

It has also driven expectations of new ways to connect to health services and greater expectations and understanding from New Zealanders and the potential for delivery of support and services across Aotearoa.

Also, the rapid development of effective and safe vaccines during the pandemic represents an unprecedented collaboration between researchers, industry, clinicians and Government. In driving new vaccine technologies, such as mRNA vaccines, it has provided us with new gene-based tools to fight not only COVID-19 but future pandemics and seasonal illnesses like influenza.

Therapeutic Products Bill

The Therapeutic Products Bill is an integral part of the health and disability reforms.

The Medicines Act 1981 has not kept pace with changes in policy, clinical practice, or technological advances. The Therapeutic Products Bill seeks to address these challenges.

The Bill, which covers medicines, medical devices, biologics, cell and tissue therapies, and natural health products, is a key Government priority. The Bill is expected to be introduced to Parliament in late 2022.

The Bill will help deliver better health outcomes for people and ensure consumer safety. It will provide New Zealanders with the assurances they would expect about the quality,

safety and efficacy of therapeutic products and devices, and the quality and safety of natural health products.

To keep pace with the discoveries already made, and those advances still to come, New Zealand needs a new therapeutic products regime that provides for the comprehensive, flexible, robust, and risk-proportionate regulation of medicines, medical devices, biologics and cell and tissue therapies.

Further work on the Bill has focused on addressing sector feedback from the public consultation in 2019, the current work underway on the health and disability system reforms, as well as new health technology changes and lessons from COVID-19.

The new regulatory regime will operate as part of a transformed health and disability system. It will enable service innovation, particularly in primary care and community settings. It will also align with international best practice and will be future proofed with flexibility to support innovation and ensure effective control over new technologies.

Te Tiriti and equity

The Bill will embed the principles of Te Tiriti which will mean that we never lose sight of the need to deliver and provide for equitable health outcomes.

We want to ensure the new regulator can build productive Māori-Crown relationships and ensure the development and administration of the wider therapeutic products regulatory regime has an appropriate equity lens.

Genomic medicine

Turning now to genomic technology – which is rapidly expanding in testing, sequencing and genetic modification techniques (such as CRISPR), and may give rise to new treatments and interventions.

Products involved in genomic medicine intended for a therapeutic purpose will be regulated under the Bill through their appropriate product categories. For example,

gene therapies and advanced cell-based therapies (such as CAR-T personalised cancer treatments) are defined as 'biologics' (i.e., the class of therapeutic products that are or contain human cells or tissues) and will be regulated as medicines. Genetic testing kits used at home or in a clinical setting will likely be regulated as medical devices.

Under the Bill, these products will be assessed by the regulator in a risk-proportionate manner to ensure safety, quality and efficacy for genomic medicines for market authorisation.

New and bespoke pathways will be designed for novel genomic medicines and their clinical trials will be regulated as a controlled activity requiring a licence or permit.

The therapeutic product regime for biologics will run in parallel with other regulatory approval processes, including approval through the Environmental Protection Authority for all genetically modified organisms under the Hazardous Substances and New Organisms Act, and existing ethics approval processes.

Where appropriate, the product will be aligned with other regimes involving human cells and tissues and genetic information, including the Human Tissue Act and the Human Assisted Reproductive Technology Act.

[Content to be signed off by Minister's office]

Therapeutic Products Bill updates

New regulator

As part of the new therapeutic products regime, the new regulator will cover a broader scope of products and activities than Medsafe - for example, medical devices, advanced therapies, natural health products and clinical trials.

It will be responsible for ensuring the safety, quality and efficacy of regulated products across their lifecycle. It will design and implement proportionate risk-based market authorisation pathways to support the timely availability of products. Its functions will include market authorisation, licensing, monitoring, compliance, and enforcement.

The new regulator will be a branded business unit within the Ministry of Health, with an independent statutory officer appointed to undertake specific regulatory functions. It will recover its costs largely through fees and levies, similar to Medsafe.

Modern enforcement tools

The Bill also includes a range of enforcement tools that include tiered criminal offences, strict liability offences, improved infringement notices and a civil pecuniary penalty regime. Promoting trust and confidence in the new regulatory regime is crucial.

DTCA-PM

I know some of you will be interested in an update on Direct to Consumer Advertising for Prescription Medicines (DTCA-PM).

DTCA-PM has several benefits: it can lead to more awareness of health conditions and earlier detection of diseases, increased literacy, and better relationships between prescribers and patients. GPs report being confident about resisting patient pressure to prescribe particular medicines.

In New Zealand advertising for medicines, medical devices and medical treatments is regulated through government regulation and self-regulation by industry and professional organisations. Only minimal enforcement is currently needed, suggesting the combination of government regulation and self-regulation is effective.

The Therapeutics Product Bill contains an enhanced status quo. It continues allowing well-regulated DTCA-PM and will provide the regulator with more modern and effective enforcement tools.

Pharmac Review

Lastly, turning to Pharmac, you'll be aware that the Pharmac Review was released earlier in June. The review looked into whether Pharmac makes the best contribution to improving health outcomes for all New Zealanders, particularly Maori and Pacific peoples.

The review has been an opportunity to ensure Pharmac is well positioned for our future health needs. While the review found that Pharmac performs an important role and New Zealanders benefit from its work - its purpose, its performance needs to improve, especially on equitable outcomes. Pharmac needs to be far more integrated into the health system. Its work and information needs to be more open and accessible.

Pharmac has accepted the review findings and is committed to making the significant changes needed. It has some work already underway but also recognises there is considerably more to do.

Closing

We've made good progress in developing the systems and structures needed to support our health system and the wellbeing of New Zealanders. However, this is only the beginning. There is still a lot of mahi ahead.

The reforms will take time to bed in, but I'm encouraged with the progress to date. The building blocks are in place, the commitment is there, and the momentum is there.

It's going to take all of us working together to achieve pae ora for all New Zealanders, and I look forward to continuing this journey alongside you.

Nō reira, tēnā koutou, tēnā koutou, tēnā tātou katoa.

Appendix Three

1. Medicines New Zealand media release - 19 May 2022

Budget 2022 Medicines Investment: A start, but also a potential rapid and painful stop?

Announcement in the budget of $191 million of new investment for medicines over the next two years is a start, but the fact that there is no confirmed additional investment beyond those two years is both a risk and concern, especially when compared to most other health packages in this year's budget where four years of investment was confirmed. It also shows the Government is starting to partially honour its commitment to improving New Zealand's access to medicines and patients' wellbeing. This action today will also start to help solve both the medicines access crisis and medicines inequity issues for Māori and Pacific peoples.

The establishment of a defined medicines appropriation in Budget 2022, has also now made it clear the level of medicines investment is only 5% of the total health portfolio. This investment level will continue to see New Zealand at the bottom of the OECD rankings compared to our peer nations such as Australia and the UK where the investment level is over 10%.

"This should be a concern, as polls show that 90% of New Zealanders believe that medicines are an important part of an effective public health system. Clearly, lower levels of investment in medicines has knock-on effects, as it is well established that modern medicines reduce pressures upstream in health systems, by lowering hospitalisation rates, and reducing mortality, as well as allowing patients to become an active part of their whānau and community again". Says Dr Graeme Jarvis, CEO of Medicines New Zealand

New Zealand's well-established extensive backlog of medicines sitting on various waiting lists to be publicly funded including some that are still waiting up to ten years or more due to funding shortfalls, and a further 73 medicines on the Options for Investment (OFI) List requiring over $400 million per year in additional public funding to clear it, also reinforces the problem and other issues with the medicines procurement system.

"While the new funding commitments to grow the medicines budget can slowly start to clear this backlog of recommended medicines on these lists - there is much more to be done. The modern medicines industry remains committed to assisting the Government after the Pharmac Review's final report is released to deliver the right solutions to the most critical stakeholders in the public health system- patients and their whānau '' says Dr Jarvis.

END

2. Medicines New Zealand media release – 1 June 2022

Pharmac review: a step in the right direction, but 'devil will be in the detail' for government on actions to be taken.

Medicines New Zealand believe that the final report of the Independent Pharmac Review panel is a step in the right direction. There is, however, much more work to be done as the Government's response has not clearly stated how it will act on the recommendations made for the improvement of New Zealand's publicly funded medicines funding system.

The report's 33 recommendations clearly show the need for Pharmac to focus on enhanced equity, more transparency and timeliness regarding medicines procurement processes for the benefit of both patient health and wellbeing outcomes and to help optimise efficiencies in the public health system.

"A number of the recommendations, if fully adopted, such as improved patient engagement and embedding equity principles into aspects of decision-making are pleasing to see. This could see more transparent, timely, and equitable processes and outcomes from Pharmac in the near term and into the future" says Dr Graeme Jarvis, CEO of Medicines New Zealand.

"The Minister of Health has stated that the Government rejected only two of the recommendations and therefore accepted the majority of the recommendations in the report. However, it is not clear what actions the Government is taking on the remaining recommendations or which ones they accept in full or in part or are modifying further. Therefore the 'devil will be in the detail' and something that all stakeholders need to observe closely."

"The Review Panel has acted with great integrity and despite its limited scope delivered a very comprehensive and strong plan of action for positive change for patients. It is important that the Government takes on board as many of the recommendations made by the Panel in full for overall system improvements. As to ignore some of their recommendations "waters down" the potency of the plan. "

"Any cherry-picking of recommendations or meaningless actions by the Government would have major impacts not only on patient health outcomes and wellbeing, but also would further impact the health system performance and efficiency. That would be in no-one's interest."

END

Appendix Four: Biography of panel members

Richard Vines
Founder and Chairman
Richard attended University of Melbourne where he studied Maths and Statistics. He then trained as an Actuary but was seduced by the fledgling IT industry before qualifying. After several years working in software development, Richard formed his own software company which he then sold in 1990 before embarking on a second software venture in Europe.

In 1996, Richard returned to Australia where he was retained by an American company to establish a sales channel in Australia. In 2001 Richard left the IT industry and has since worked in a number of not-for-profits associated with retail, politics and health.

In 2012 Richard and his wife Kate established Rare Cancers Australia, a patient advocacy group whose mission is to improve the lives and outcomes for rare cancer patients. Richard is now a highly sort after spokesperson for cancer patient advocacy issues and is a member of a number of committees.

In September this year, Richard was named Co-Chair of the Cancer Drugs Alliance Committee, a stakeholder coalition tasked to promote timely access to drugs for cancer patients.

Professor David Thomas
NHMRC Principal Research Fellow and CEO of Omico: the Australian Genomic Cancer Medicine Centre.

David undertook medical training at the University of Melbourne (1982-88), followed by post-graduate training as a Fellow of the Royal Australasian College of Physicians in medical Oncology (awarded 1997). His doctoral studies at the Universty of Melbourne, and was awarded my PhD in 1997.

He undertook post-doctoral research at Harvard Medical School (1998-2000), before moving back to Melbourne to set up his own laboratory, initially at St Vincent's Hospital (2001-3), then at Peter MacCallum Cancer Centre (2002-2014).

David was the founding Chair and board member of the Australasian Sarcoma Study Group (2007-18). He was the Director of the adolescent and young adult (AYA) cancer program, onTrac@PeterMac (2005-10). In 2018, he was the President of the Connective Tissue Oncology Society. He was head of the Cancer Theme at the Garvan Institute (2014-20).

In 2018, David established Omico, the Australian Genomic Cancer Medicine Centre**.**

Professor Cris Print
Professor in the University of Auckland's Department of Molecular Medicine and Pathology. He holds a medical degree and PhD from the University of Auckland and his current work centres around the use of genomics and bioinformatics to understand cancer.

His research team apply cutting-edge techniques in these fields to the Maurice Wilkins Centre's 'Immuno-oncology' flagship programme. He leads the Genomics Into Medicine Strategic Research Initiative in Auckland and Chairs the Auckland Regional Tissue Bank Scientific Advisory Board.

He is a Director of the NZ Institute of Environmental Science and Research (ESR), Vice President of the Auckland branch of the Royal Society of NZ (The Auckland Museum Institute) and is a member of the Science Leadership Team of New Zealand's 'Healthier Lives' National Science Challenge. Previously, he served as President of the NZ Society for Oncology and was Director of the Bioinformatics Institute at the University of Auckland.

Assoc. Prof. Māui Hudson
Iwi: Te Whakatohea, Ngā Ruahine, Te Mahurehure
Māui is an interdisciplinary researcher who focuses on the application of mātauranga Māori to decision-making across a range of contemporary contexts from new technologies to health, the environment to innovation.

He has co-authored a number of ethical guidelines including Te Ara Tika: Guidelines on Māori Research Ethics, a framework for researchers and ethics committee members; Te Mata Ira Guidelines on Genomic Research with Māori; and He Tangata Kei Tua Guidelines on Biobanking with Māori.

Māui's current research projects include:

- *Te Nohonga Kaitiaki* - developing Guidelines for Genomic Research with Taonga Species
- *Co-Innovation Interface* - exploring Māori perspectives on gene editing
- *Te Tuakiri o te Taonga* - developing Biocultural Labels to recognise indigenous rights in genomic data
- *He Papa Moana* - developing a cross cultural ocean knowledge platform as part of the Moana project
- *Māori IP & Responsible Innovation* - understanding the intersection between intellectual property and Indigenous data sovereignty.

Māui supports Māori to engage in the research sector as a co-convener of SING Aotearoa, the New Zealand chapter of the Summer Internship for Indigenous Genomics, and Te Ahu o Rehua, a Network for Cross Cultural Ocean Knowledge connecting expertise across the fields of climate change, marine science, ocean health, voyaging and non-instrument navigation. Māui also advocates for Māori rights and interests through Te Mana Raraunga: Māori Data Sovereignty Network and the Global Indigenous Data Alliance. He is a co-founder of ENRICH, a joint initiative between the University of Waikato and New York University, and a co-developer of the Biocultural Labels Initiative.

END.

Document 6

Aide-Mémoire

Meeting with the Medical Technology Association of New Zealand

Date due to MO:	15 November 2022	**Action required by:**	N/A
Security level:	IN CONFIDENCE	**Health Report number:**	H2022016300
To:	Hon Andrew Little, Minister of Health		
Consulted:	Health New Zealand: ☐ Māori Health Authority: ☐		

Contact for telephone discussion

Name	Position	Telephone
John McGrath	Director, Priority Projects Strategy Policy and Legislation	S9(2)(a) [redacted]
Steve Waldegrave	Associate Deputy Director-General Strategy Policy and Legislation	

Document 6

Aide-Mémoire

Meeting with the Medical Technology Association of New Zealand

Date due:	15 November 2022		
To:	Hon Andrew Little, Minister of Health		
Security level:	IN CONFIDENCE	**Health Report number:**	H2022016300

Details of meeting: 11:30 – 12 pm, 16 November 2022 at your office

Purpose of meeting/ proposal: You are meeting with members of the Medical Technology Association of New Zealand (MTANZ). MTANZ wants to discuss the future regulation of medical devices under the Therapeutic Products Bill, industry views on Health Technology Assessment and procurement of medical devices.

Comment:

Meeting with MTANZ

- MTANZ is the leading industry body representing medical technology manufacturers, importers and distributers of medical devices in New Zealand.
- You are meeting with Cushla Currie, Chief Executive Officer of MTANZ; Erin Currie, Board Chairperson and two MTANZ members. Officials from Manatū Hauora - Ministry of Health (the Ministry) will also attend. Meeting details including attendees are provided in **Appendix 1**. **Appendix 2** contains short bios of members of the MTANZ delegation.
- MTANZ informed the Ministry of topics they wish to discuss with you, including the medical device industry's role in the healthcare sector in Aotearoa, future regulations of medical devices under the Therapeutic Products Bill, Health Technology Assessment and Pharmac's procurement of medical devices. This aide-mémoire provides you with some background information on these matters and talking points (**Appendix 3**) to support you.
- This aide-mémoire discloses all relevant information.

Steve Waldegrave
Associate Deputy Director-General
Strategy Policy and Legislation

Purpose

1. MTANZ has advised the Ministry that their primary focus for the meeting is to discuss:
   a. MTANZ's general support for the Therapeutic Products Bill (the Bill) and support for a "light touch" regulatory regime for medical devices
   b. MTANZ's views on Health Technology Assessment
   c. Pharmac's role in the procurement of medical devices.
2. Attached are meeting details (**Appendix 1**), short bios on MTANZ attendees (**Appendix 2**) and talking points to support you at this meeting (**Appendix 3**).

Background and context

3. MTANZ is the leading industry body representing medical technology manufacturers, importers and distributers of medical devices in New Zealand. Its members supply approximately 95 percent of all medical device products used in New Zealand public and private healthcare facilities.
4. In July 2022, Manatū Hauora presented on the Bill and the future regulation of medical software at the MTANZ-organised HealthTech Week conference in Auckland. This conference included representatives from MTANZ. Questions and comments from attendees were generally supportive of the intention of the Bill but sought further information on transitional arrangements for currently available products and cost recovery.

What regulation of medical devices under the Bill will look like

5. MTANZ is likely to advocate aligning our medical device regime with international norms. Such an approach was reflected in the 2018 exposure draft Bill and continues to be the case. Since the 2018 public consultation, the Ministry has focused on strengthening provisions in the Bill to improve international alignment.
6. Specifically for medical devices, the Bill adopts internationally aligned definitions that are significant in determining the scope for regulating medical devices and market players, such as responsible manufacturers, remanufacturers and sponsors who are subject to obligations under the Bill.
7. The Bill empowers regulation and rule-making including risk classification rules modelled on the International Medical Device Regulators Forum's rules and other advanced medical device regulators' practices. Product standards for different types of medical devices will be set out in regulations and rules. MTANZ previously expressed that regulation of clinical trials should be risk-proportionate, timely and not duplicate

processes to drive innovation in health technologies. The Bill's definition of clinical trial is internationally aligned and is intended not to duplicate existing ethics approval processes.

Health Technology Assessment

8. The World Health Organisation defines Health Technology Assessment (HTA) as a systematic and multidisciplinary evaluation of the properties of health technologies and interventions covering both their direct and indirect consequences.

9. New Zealand has a strong and robust HTA scheme for medicines under the Medicines Act 1981 (Medicines Act) and Medsafe has developed modern and pragmatic evaluation pathways for medicines. However, the Medicines Act currently provides insufficient coverage of the many technologies used in modern healthcare delivery. One current example is the lack of regulatory processes for evaluating COVID-19 Point-of-Care Test products and practices. This causes major delays in providing them to the public.

10. Under the Bill, medical devices will be subject to a similar HTA. The HTA for medicines and medical devices will be a main component of the market authorisation framework under the Bill and an important role for the new regulator.

11. MTANZ may want to discuss how the future HTA scheme for medical devices can be streamlined with international regulators' practices and Pharmac's procurement processes. The Bill provides for the regulator to adopt international best practice and rely on trusted overseas assessments and reports. Medsafe and Pharmac have worked together with overseas regulators and it will be a core expectation of the new regulator to build on this work.

12. Details of what the medical device HTA scheme might look like and the regulator's strategy for the performance of its functions will be developed as part of the wider regulatory regime (eg, secondary legislation). MTANZ will be a key stakeholder in helping design a modern and cost-effective HTA regime for medical devices.

Pharmac's procurement of medical devices

13. The Government decided in 2012 that Pharmac would centralise and manage the procurement of medical devices. This was to provide consistent access to medical devices across New Zealand, help hospitals manage spending on medical devices in a sustainable way, and free up funding for new technology and other health initiatives.

14. Pharmac's main roles in this work include:

    a. determining which medical devices are publicly funded to get the best possible health outcomes

    b. creating and managing a national list of medical devices for hospitals to choose from

    c. managing a process to consider access to items outside of the list when exceptional circumstances require this.

15. In 2019 Pharmac consulted with then District Health Boards and around 150 medical device suppliers on "managing fairer access to hospital medical devices". It received general and specific operational feedback from stakeholders, including MTANZ. Key points from the sector were that:

a. Pharmac needs to be transparent and seek appropriate advice for their decision-making and management of the national list

b. Pharmac's approach to medical devices needs to consider the different characteristics of medical devices to those of medicines

c. Pharmac's commitment to save $1 billion for Vote Health from their management of devices may force smaller New Zealand-owned companies to leave the market, resulting in reduced patient options or access to medical devices.

16. MTANZ may want to discuss the industry's concern about Pharmac's central procurement work being implemented alongside progressing the Bill. You may want to acknowledge that these two Government initiatives are likely to generate additional demands for the industry over the next couple of years as the Bill, and its subordinate legislation, and Pharmac's medical devices procurement work progress.

17. The Ministry and Pharmac intend to take a gradual approach to implementing these new initiatives (eg, transitional arrangements are provided for medical devices under the Bill) and officials will continue to work closely together with the industry in this space.

Other areas of interest

18. The following information has not been made publicly available and provided for your information only for the purpose of this meeting.

19. **Introduction of the Bill** – MTANZ may ask when the Bill will be introduced and enacted. Once the Bill is introduced this year, and passes through the House, development of secondary legislation (eg, regulations, rules and regulator's notices) will likely take two to three years and will include extensive public and targeted consultation. The Bill currently includes a commencement date of 1 September 2026.

20. **Transitional arrangements** – During consultation on the 2018 exposure Bill the medical device sector requested a longer transition period for currently available products to apply for and receive a market authorisation. This has been reflected in the revised Bill. The Bill now allows a three to five-year window for medical devices, depending on their assessed risk.

21. **Form of the regulator** – MTANZ considers that the regulator should be independent and 'accountable'. In 2021, Cabinet authorised the Bill to establish an independent statutory officer within the Ministry and confer functions, powers and responsibilities on them [CBC-21-MIN-0017]. This information has yet to be released.

22. **Cost recovery, fees, charges and levies** - MTANZ may ask how costs will be recovered from industry and whether establishment costs should be funded by the Government. Decisions on funding for establishment costs have not been made yet. Following the decision made by Cabinet in 2021 [CBC-21-MIN-0017], the Bill authorises cost recovery through fees, charges and levies to be developed in regulations based on certain principles. The costs of establishing the regulator, the regulatory scheme and any staging of fees during the transition period are still to be determined. The Ministry will consult with MTANZ and other stakeholders on cost recovery during the development of the regulations.

23. MTANZ plans to host a workshop with their industry regulatory affairs group in December in Auckland and has invited officials from the Ministry to attend to discuss industry engagement plans and the development of regulations.

Appendix 1 – About the meeting

Purpose	This memo provides you with information to support a meeting with Medical Technology Association New Zealand (MTANZ). MTANZ wants to discuss a range of matters about the future regulations of medical devices under the Therapeutic Products Bill and Pharmac's procurement model for medical devices.	
Meeting/visit details	**Date:**	16 November 2022
	Time:	11:30 to 12 pm
	Venue:	At your office
Attendees	Erin Currie – Chair of the MTANZ Board and Country Manager NZ Philips Healthcare John Matthews – Member of the MTANZ Board and NZ Manager EBOS Healthcare Cushla Currie – Chief Executive, MTANZ Mike Munley – Head of Government Affairs and Policy, MTANZ	
Organisation	Medical Technology Association New Zealand (MTANZ)	
Ministry representatives	John McGrath Director, Priority Projects, Strategy Policy and Legislation S9(2)(a) [redacted] Derek Fitzgerald Manager, Compliance Management Branch, Medsafe S9(2)(a) [redacted]	
Other information	NA	

Appendix 2 – Biographies of attendees from MTANZ

Erin Currie – President and Chair of the Medical Technology Association of New Zealand (MTANZ) since Aug 2017	
	Erin is an experienced business and governance leader, with 30 years' experience in the healthcare sector. Her knowledge and expertise are in medical devices, equipment and digital healthcare across radiology, surgical specialties, cardiology, gastroenterology, and endoscopy. Erin's career commenced as a registered nurse, with a later move into medical device sales, where she developed her management, commercial strategy, and governance skills. She is New Zealand Country Manager for Philips Health Systems, part of the Australia-New Zealand leadership team, after joining in November 2020. Her previous roles included six years leading Olympus New Zealand, and 10 years with Medtronic in various roles including sales, sales management, and branch leadership.
Cushla Currie – Chief Executive of MTANZ since June 2021	
	Cushla has broad health sector experience with a commercial focus. She started her career as a registered nurse and subsequent roles have included senior positions in health in international business development, clinical research, procurement and supply chain (private and public) and human resources. Amongst other current roles, Cushla is a member of the Enhancing New Zealand's Clinical Trials Steering Committee (Health Research Council and Ministry of Health) and a member of the Pathology Awareness Australasia Steering Group Committee (a group that represents interests across the field of pathology).

John Matthews – member of MTANZ Board	
	John has 27 years' experience in healthcare supply, including the management of hospital/primary care/aged care facilities in New Zealand and Australia. He is currently the New Zealand Manager of EBOS Healthcare.
Mike Munley – Head of Government Affairs and Policy, MTANZ	
	Mike is a senior healthcare executive with international experience in multi-national corporates, start-ups and not-for profits that spans governance, marketing, strategy and business development, new product development and international market management.

Appendix 3 – Talking points

The new regulatory scheme

- The Bill is a priority for the government and will be introduced to Parliament this year.
- The Bill supports risk proportionate regulation, where the regulation of a product is proportionate to a product's benefits and risks.
- The Bill will align our regulatory framework for therapeutic products (including medical devices) with international norms. For example, the Bill adopts internationally aligned definitions that apply to medical devices and clinical trials involving medical devices.
- It is intended that regulations and rules made under the new Act (including risk classification rules) will be modelled on the International Medical Device Regulators Forum's rules and other advanced medical device regulators' practices.
- Once enacted there will be a two to three-year period to develop key secondary legislation. I encourage you to work with the Ministry and new regulator to help make the new regime a success.

Transition period

- Officials considered your sector's concern around the insufficient transitional time given for medical devices. I will have more to say on this in the coming weeks.

Form of the regulator

- I will have more to say on this in the coming weeks.

Cost Recovery

- The Bill contains requirements that fees and charges be set through secondary legislation (regulations and rules), which ensures that the sector and public are consulted during their establishment and that the fee or levy is subject to scrutiny by Cabinet.
- MTANZ and other stakeholders will be consulted during the development of regulations relating to fees and levies.

Pharmac's procurement of medical devices

- Pharmac's work to centralise medical devices procurement is essential if we are to enable fairer access to devices across all hospitals. This is fundamental to the Government's vision for pae ora/healthy futures and to ensure that healthcare spending achieves the best possible outcomes.
- Both the reform of the therapeutic products regime and Pharmac's work will require significant input from the industry, especially when the development of operational and technical details of secondary legislation begins, and Pharmac's medical devices procurement work progresses over the next few years.