Hon Casey Costello

Minister of Customs
Minister for Seniors
Associate Minister of Health
Associate Minister of Immigration
Associate Minister of Police

25 July 2024

Tessa
fyi-request-27300-c5c65827@requests.fyi.org.nz

Dear Tessa

Response to your request for official information

I acknowledge your request under the Official Information Act 1982 (the Act) on 19 June 2024 you requested

> *any advice you have received this calendar year regarding changes to the regulation of medical devices.*

I have interpreted your request to include Cabinet papers, briefings, aides memoire and memos relating to the repeal of the Therapeutics Products Act 2023 and replacement legislation.

All documents identified in scope of your request are itemised in Appendix 1 and copies of the documents are enclosed.

Where information is withheld, this is outlined in the Appendix and noted in the document itself. Where information is withheld under section 9 of the Act, I have considered the countervailing public interest in release in making this decision and consider that it does not outweigh the need to withhold at this time.

> *In addition, I request any advice you have received in the same time period regarding the performance of current regulations relating to medical devices.*

Under the Medicines Act 1981, medical devices are subject to only minimal regulation and these have not been subject to any formal performance benchmarking. As such, your request for information on 'the performance of current regulations relating to medical devices' is refused under section 18(e), as the information does not exist. However, documents already publicly released, for example the Cabinet paper on repealing the Therapeutic Products Act, reflect on the sufficiency of current medical device regulation.

Cabinet material relating to the repeal of the TPA is publicly available on the Ministry of Health's website at: www.health.govt.nz/about-ministry/information-releases/release-ministerial-decision-making-documents/cabinet-material-repealing-therapeutic-products-act.

Documents relating to the regulation of medicines are also publicly available on the Ministry of Health's website at: https://www.health.govt.nz/our-work/regulation-health-and-disability-

system/regulating-medicines-medical-devices-and-natural-health-products/documents-relating-regulation-medicines-medical-devices-and-natural-health-products.

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.

Yours sincerely,

Hon Casey Costello
Associate Minister of Health

Appendix 1: List of documents for release

#	Date	Document details	Decision on release
1	7 February 2024	Briefing Cabinet paper: Progressing the repeal of the Therapeutic Products Act – a proposed reset for health product regulation (H2024035378)	Some information withheld under section 9(2)(a), to protect the privacy of natural persons. Information deemed out of scope of your request has also been excluded.
2	13 February 2024	Aide-Memoire: Meeting with Medical Technology Association of New Zealand (H2024036005)	Publicly available at: www.health.govt.nz/about-ministry/information-releases/release-ministerial-decision-making-documents/advice-associate-minister-health-hon-casey-castello-february-2024.
3	28 February 2024	Briefing: Final Cabinet paper for lodging, and talking points: Progressing the Government's commitment to repeal the Therapeutic Products Act (H2024035986)	Some information withheld under the following sections of the Act: • 9(2)(a); and • 9(2)(f)(iv) to maintain the constitutional conventions that protect the confidentiality of advice tendered by Ministers and officials.
4	29 February 2024	Briefing Women's health delegation (H2024035860)	Publicly available at: www.health.govt.nz/about-ministry/information-releases/release-ministerial-decision-making-documents/advice-associate-minister-health-hon-casey-castello-february-2024.

5	15 March 2024	Briefing Revised Cabinet paper - Repealing the TPA (H2024037132)	Some information withheld under section 9(2)(a) of the Act. Information deemed out of scope of your request has also been excluded.
6	11 April 2024	Briefing: Advice on an active petition relating to Essure, a permanent contraceptive medical device (H2024038651)	Refused under section 18(d) of the Act as the document will soon be made publicly available here: www.health.govt.nz/about-ministry/information-releases.
7	23 April 2024	Briefing: Cabinet paper on repealing the Therapeutic Products Act 2023 (H2024039302)	Some information withheld under the following sections of the Act: • 9(2)(a); and • 9(2)(f)(iv). Information deemed out of scope of your request has also been excluded.
8	13 May 2024	Briefing Medical products regulatory reform work programme (H2024039024)	Some information withheld under the following sections of the Act: • 9(2)(a); and • 9(2)(f)(iv). Information deemed out of scope of your request has also been excluded.
9	13 June 2024	Briefing Therapeutic Products Act Repeal Bill: Approval to lodge Cabinet Paper (H2024042381)	Some information withheld under the following sections of the Act: • 9(2)(a); and • 9(2)(f)(iv). Information deemed out of scope of your request has also been excluded.

Document 1

MANATŪ HAUORA
MINISTRY OF HEALTH

Briefing

Cabinet paper: Progressing the repeal of the Therapeutic Products Act – a proposed reset for health product regulation

Date due to MO:	7 February 2024	**Action required by:**	8 February 2024
Security level:	IN CONFIDENCE	**Health Report number:**	H2024035378
To:	Hon Casey Costello, Associate Minister of Health		
Copy to:	Hon Dr Shane Reti, Minister of Health		
Consulted:	Health New Zealand: ☐	Māori Health Authority: ☐	

Contact for telephone discussion

Name	Position	Telephone
Maree Roberts	Maree Roberts, Deputy Director-General, Strategy, Policy and Legislation	s 9(2)(a) [redacted]
Tim Vines	Manager, Therapeutics, Strategy, Policy and Legislation	

Minister's office to complete:

☐ Approved ☐ Decline ☐ Noted

☐ Needs change ☐ Seen ☐ Overtaken by events

☐ See Minister's Notes ☐ Withdrawn

Comment:

Document 1

Cabinet paper: Progressing the repeal of the Therapeutic Products Act – a proposed reset for health product regulation

Security level:	IN CONFIDENCE	**Date:**	8 February 2024
To:	Hon Casey Costello, Associate Minister of Health		

Purpose of report

1. This briefing provides you with a draft Cabinet paper that provides Cabinet with an update on your work to repeal the Therapeutic Products Act (TPA) and seeks agreement to develop policy for future regulation of health products. This briefing seeks your approval to commence agency and Ministerial consultation from the afternoon of 9 February 2024, or no later than midday 12 February.
2. This briefing also provides you with additional information on the next steps for progressing the Cabinet paper, including steps that your Office will need to take.
3. This report discloses all relevant information and implications.

Summary

4. On 29 November 2023, Cabinet agreed to the Coalition Government's 100 Day Plan [CAB-23-MIN-0468]. The Plan included an invitation for you to report back within the 100 days (by 8 March 2024) on work to begin to repeal the TPA.
5. On Monday 29 January, you met with officials to discuss the implications of repealing the TPA. At that meeting, you outlined your view that the repeal of the TPA should not result in a loss of momentum in progressing necessary and essential reforms to the regulation of medicines, medical devices and natural health products (NHPs).
6. The attached Cabinet paper (**Attachment 1**) provides Cabinet with an update on work to repeal the TPA. The paper also seeks Cabinet's agreement to developing policy for new legislation to support consumers, the health sector and industry by modernising the regulation of medicines and medical devices (collectively 'medical products'), and NHPs.
7. To meet the 100-day timeframes, consultation with Government agencies and your Ministerial colleagues will need to occur concurrently. Subject to your agreement to the draft Cabinet paper, the Ministry and your office will make this happen.
8. If Cabinet supports the development of new policy on regulatory reforms for medical products and NHPs, the Ministry will provide you with further detailed advice on the form of any new legislation required and the form and role of a regulatory entity (or entities) for all health products. This advice will be provided to you in the first half of 2024 and in advance of your report back to Cabinet in November 2024. Advice on NHPs

will require a joined-up approach with the Ministry for Primary Industries and the Environmental Protection Authority.

Recommendations

We recommend you:

a)	**Note** that Cabinet invited you to report on work to begin to repeal the Therapeutic Products Act 2023 by 8 March 2024.	**Noted**
b)	**Note** that the attached draft Cabinet paper will respond to that invitation by outlining your proposed approach to repeal.	**Noted**
c)	**Note** that the draft Cabinet paper also seeks Cabinet's agreement for new policy work on regulating medicines, medical devices and natural health products, and that this responds to your request on 29 January 2024 for the Ministry to maintain momentum on essential reforms to the regulation of these products.	**Noted**
	Either	
d)	**Agree** to circulate the draft Cabinet paper for Ministerial and agency consultation, with consultation to end 19 February 2024 [**Ministry recommendation**].	**Yes / No**
	or	
e)	**Inform** officials of any changes required to the draft Cabinet paper by 9 February 2024, with consultation to commence afterwards.	**Yes / No**

Maree Roberts
Deputy Director-General of Health
Strategy, Policy and Legislation
Date: 7 February 2024

Hon Casey Costello
Associate Minister of Health
Date:

Document 1

Cabinet paper: Progressing the repeal of the Therapeutic Products Act – a proposed reset for health product regulation

Background to the Cabinet paper

1. On 29 November 2023, Cabinet agreed to the Coalition Government's 100 Day Plan [CAB-23-MIN-0468]. The Plan included an invitation for you to report back within the 100 days (by 8 March 2024) on work to repeal the TPA.

2. In December 2023, we advised the Minister of Health that current regulatory systems for health products (medicines, medical devices, and natural health products (NHPs) are outdated, fragmented, and not fit for purpose [H2023033595]. These systems do not adequately protect consumer safety, support industry to manufacture and export high quality products, or ensure timely access to innovative products.

3. On 29 January 2024 you met with officials from the Ministry of Health to discuss progressing the repeal of the TPA and a draft Cabinet paper seeking Cabinet approval on a TPA repeal bill [H2023033302]. At this meeting we discussed the rationale for the TPA and the implications for its repeal. You expressed your desire for the repeal of the TPA to not result in a loss of momentum in progressing necessary and essential reforms to the regulation of medicines, medical devices and NHPs. Consequently, the Ministry has now drafted a Cabinet paper for your review (**Attachment 1**).

4. The Cabinet paper provides an update on work to repeal the TPA. This report will fulfil your obligation to start work to repeal the TPA as part of the Government's 100-day plan. Following the discussion on 29 January, the paper now also seeks Cabinet's agreement for policy work to commence on new legislation to regulate medicines and medical devices ('medical products'), and NHPs.

Background to the Therapeutic Products Act

5. Successive governments have worked to modernise health product regulation, with the TPA being the most recent attempt. The TPA faced some strong opposition from the NHP sector and consumers, many of whom believed that the TPA would over-regulate NHPs and make them unaffordable or inaccessible. While provisions in the TPA that applied to medicines and medical devices had more support, some industry, clinical and researcher stakeholders had concerns about elements of the TPA, including regulation of lower risk medical devices, and advertising provisions.

6. In response to these concerns, the National-New Zealand First and National-ACT coalition agreements committed to repealing the TPA.

7. At the time of the Government's announcement that it would repeal the TPA work was already underway in the Ministry to implement the TPA prior to its commencement in 2026. This work included establishing a new regulator, scoping the design of a new IT platform and developing secondary legislation. Importantly, this work also included the development of a budget bid for Budget 2024 as Government funding for the

implementation of the TPA had not been secured. All work to implement the TPA ceased last year.

8. The statutory commencement date in the TPA of 1 September 2026 was acknowledged by the Ministry and other stakeholders as highly ambitious.

There is an opportunity to reform regulation of health products

9. Repealing the TPA creates an opportunity for you to reset the legislative approaches to regulating medical products and NHPs. The Cabinet paper outlines some of these existing challenges, including that the regulation of NHPs is creating barriers to export and job growth. These have also been set out in earlier briefings [refer H2023033595].

10. The attached paper seeks Cabinet's agreement to develop policy for future regulation of health products. If Cabinet supports the development of new policy on regulatory reforms for medical products and NHPs, the Ministry will provide you with further detailed advice in the first half of 2024 on the form of any new regulations required and the form and role of a regulatory entity (or entities) for all health products.

Process

11. This section sets out the process for bringing the attached Cabinet paper to Cabinet, and for developing new policy and legislation.

Cabinet paper process

12. If you agree to commence consultation immediately, Ministerial and agency consultation will run from 8 to 19 February. Your office will forward the draft Cabinet paper to the offices of your Ministerial colleagues whose portfolios may be affected by health product regulatory reform. We recommend that the paper is sent to the offices of the Minister of Health, the Prime Minister, the Minister of Regulation; and the Ministers of Finance; Foreign Affairs and Trade; Defence; Primary Industries; Food Safety; Research, Science, and Innovation; Commerce and Consumer Affairs; Justice; Economic Development; and Māori Development. Ministers will give any feedback to your office, who will convey it to us by 19 February.

13. At the same time as Ministerial consultation, we will circulate the draft paper to relevant government departments. We will provide your office with a list of consulted agencies.

14. We will implement any changes resulting from Ministerial and departmental consultation and send you the final paper on 21 February. If you agree, we will then upload the paper to CabNet and your office will formally lodge the paper with the Cabinet Office on the morning of 22 February.

15. Your office will arrange for the paper to be considered by a Cabinet subcommittee in the week of 26 February, and by Cabinet in the week of 5 March. The Ministry will provide you with talking points for these meetings.

Policy development process

16. If Cabinet agrees to development of policy for new legislation, we will begin to give you more detailed advice on options and approaches for that legislation. Decisions will be needed on matters including:

a. the overarching principles and objectives which will guide regulatory design and selection of options

b. Out of scope [redacted]

c. the form and role of any new regulatory entity (or entities)

d. the extent to which the regulatory entity should be enabled or required to rely on decisions made by trusted overseas regulators

e. Out of scope [redacted]

f. Out of scope [redacted]

g. how health products may be promoted, including whether direct-to-consumer advertising of prescription medicines should continue

h. Out of scope [redacted]

i. Out of scope [redacted]

17. The advice will be informed by renewed engagement with key stakeholders, including representative bodies for health practitioners and the health product industries, and stakeholders in rongoā Māori. On 2 February 2024, we emailed your office a separate Communications and Engagement Plan setting out the intended approach.

18. It will also be necessary to engage with a range of Government agencies that are likely to have existing regulatory responsibilities for some health products. For example, MBIE is responsible for the sunscreen product standard; the Ministry for Primary Industries is responsible for the Food Act 2014 and the Dietary Supplements Regulations 1985, and the Environmental Protection Agency looks after the cosmetics standards.

19. Likewise, it will be necessary to engage with agencies with a special interest in how health products are to be regulated, including Customs, the New Zealand Defence Force and Corrections. We will work with the Ministry for the Environment on the interface with the Hazardous Substances and New Organisms Act 1996, for example around gene editing and genetically modified organisms.

Legislation process

20. Once you have made key decisions on the form and content of new legislation, you will seek Cabinet's approval of these policy decisions, and agreement to issue drafting instructions to Parliamentary Counsel Office (PCO). PCO will then prepare the required legislation. We will provide further advice on the post-introduction process as required.

Risks and challenges

21. On 29 January 2024 you reiterated your desire for this paper to be considered by Cabinet within the first 100 days. There is limited time to finalise and lodge the Cabinet paper for it to be considered as part of the 100-day plan. We therefore recommend that

agency and ministerial consultation occur concurrently and commence immediately (ie, 7 February 2024). You can continue to provide us feedback on the Cabinet paper up until it is lodged on 22 February.

22. Longer term, there will be a number of challenges with developing and implementing new regulation for medicines, medical devices and NHPs. Successive governments have attempted to reform regulation of health products for the last 30 years, without success.

23. A key reason for the failure of successive reform attempts is controversy surrounding regulation of NHPs. This issue can be partly addressed by separating the regulation of NHPs from the regulation of medicines and medical devices. While some stakeholders in the sector are philosophically opposed to any regulation, many manufacturers and consumer representative groups agree that some form of regulation is required to ensure products are safe to use.

24. Subject to Cabinet's decisions and the scope of future work, new funding will be needed for the development of any new regulatory regime. We will provide you with further advice on implementation options, including funding later this year.

Next steps

25. If you agree, we will begin departmental consultation on the attached draft Cabinet paper, and your office will begin Ministerial consultation. If your office forwards any feedback to us by 19 February, we will send you a final version on 21 February.

26. We will provide you with options on post-Cabinet communications when we seek your approval to lodge the final Cabinet paper.

ENDS.

Document 1

Minister's Notes

Document 3

MANATŪ HAUORA
MINISTRY OF HEALTH

Briefing

Final Cabinet paper for lodging, and talking points: Progressing the Government's commitment to repeal the Therapeutic Products Act

Date due to MO:	28 February 2024	**Action required by:**	N/A
Security level:	IN CONFIDENCE	**Health Report number:**	H2024035986
To:	Hon Casey Costello, Associate Minister of Health		
Copy to:	Hon Dr Shane Reti, Minister of Health		
Consulted:	Health New Zealand: ☒	Māori Health Authority: ☒	(on Cabinet paper)

Contact for telephone discussion

Name	Position	Telephone
Maree Roberts	Maree Roberts, Deputy Director-General, Strategy, Policy and Legislation	s 9(2)(a)
Tim Vines	Manager, Therapeutics, Strategy, Policy and Legislation	

Minister's office to complete:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Comment:

Document 3

Final Cabinet paper for lodging, and talking points: Progressing the Government's commitment to repeal the Therapeutic Products Act

Security level:	IN CONFIDENCE	**Date:**	28 February 2024
To:	Hon Casey Costello, Associate Minister of Health		

Purpose of report

1. This briefing provides you with:
   a. the final version of the Cabinet paper 'Progressing the Government's commitment to repeal the Therapeutic Products Act – a proposed reset for health product regulation'
   b. talking points for Cabinet.

Cabinet paper

2. On 29 January 2024, you requested a revised Cabinet paper on progressing the repeal of the Therapeutic Products Act 2023. You also expressed your desire for the Ministry to maintain momentum for modernising the regulation of medicines and medical devices. We provided you with a draft paper on 8 February 2024 [H2024035378].
3. We consulted on the paper with the Ministry of Business, Innovation and Employment (MBIE); the Ministry of Primary Industries; Te Puni Kokiri; Te Arawhiti; the Department of Prime Minister and Cabinet; the Parliamentary Counsel Office; the Ministry of Foreign Affairs and Trade; Health New Zealand | Te Whatu Ora; the New Zealand Customs Service; the Ministry of Justice; the Treasury; the Commerce Commission; Pharmac; the Environmental Protection Authority; Whaikaha | Ministry of Disabled People; and the New Zealand Blood and Organ Service.
4. We also circulated the paper to the Department of Corrections, Te Aka Whai Ora | the Māori Health Authority, and the New Zealand Defence Force. The Defence Force has previously advised that it supports the development of modern legislation to replace the Medicines Act 1981.
5. s 9(2)(f)(iv) [redacted]
6. [redacted]

s 9(2)(f)(iv) [redacted]

7. We will therefore lodge the paper in the CabNet database by 10am on Thursday 29 February 2024, to enable it to be considered by Cabinet on 4 March. This will fulfil your commitment to report back to Cabinet within the Government's first 100 days on starting work to repeal the Therapeutic Products Act [CAB-23-MIN-0468].

8. Talking points have been prepared to assist your presentation to Cabinet (Appendix 1).

Recommendations

We recommend you:

a)	**Note** that departmental consultation has been carried out on the paper which we provided to you in draft form on 8 February 2024, and that a final version of the paper is attached to this briefing	**Noted**
b)	**Note** that we will lodge the paper in the CabNet database by 10am on Thursday 29 February, which will enable it to be considered by Cabinet on 4 March	**Noted**
c)	**Note** that talking points have been included at Appendix 1, to assist you to present the paper to Cabinet	**Noted**

Maree Roberts
Deputy Director-General of Health
Strategy, Policy and Legislation
Date: 28/2/24

Hon Casey Costello
Associate Minister of Health
Date:

Document 3

Appendix 1: Talking points

- This paper progresses the Government's commitment to begin work to repeal the Therapeutic Products Act 2023 ('TPA').
- We have listened to the huge numbers of people who said the TPA would over-regulate the natural health products that many ordinary New Zealanders rely on every day.
- We have also heard from industry groups concerned that the TPA imposed heavy-handed obligations.
- We will repeal the TPA before it takes effect in September 2026. I am mindful, though, that the current laws that regulate medicines and medical devices are out of date.
- We have time to develop and pass new legislation to modernise the regulation of medicines, medical devices, and natural health products, that strikes the right balance.
- Resetting the approach to regulating health products will mean:
  - New Zealanders can benefit from advances in medical technology and new treatments
  - our health system and health workforce can be more efficient
  - our innovators and exporters can access new markets and take New Zealand-made products to the world.
- While the TPA got the balance wrong, we should not lose all the momentum for change. We can develop sensible, risk-proportionate legislation which protects public health, without creating unnecessary red tape.
- I plan to report back to Cabinet later this year with more detailed proposals. I will work closely with my colleagues, particularly the Minister for Food Safety and the Minister for the Environment, both of whom are currently responsible for the regulation of some natural health products.

ENDS.

Document 5

MANATŪ HAUORA
MINISTRY OF HEALTH

Briefing

Revised Cabinet paper: Repealing the Therapeutic Products Act

Date due to MO:	15 March 2024	**Action required by:**	2 April 2024
Security level:	IN CONFIDENCE	**Health Report number:**	H2024037132
To:	Hon Casey Costello, Associate Minister of Health		
Copy to:	Hon Dr Shane Reti, Minister of Health		
Consulted:	Health New Zealand: ☐ Māori Health Authority: ☐		

Contact for telephone discussion

Name	Position	Telephone
Maree Roberts	Deputy Director-General, Strategy, Policy and Legislation	s 9(2)(a) [redacted]
John McGrath	Director, Priority Projects, Strategy, Policy and Legislation	

Minister's office to complete:

☐ Approved ☐ Decline ☐ Noted

☐ Needs change ☐ Seen ☐ Overtaken by events

☐ See Minister's Notes ☐ Withdrawn

Comment:

Document 5

Revised Cabinet paper: Repealing the Therapeutic Products Act

Security level:	IN CONFIDENCE	**Date:**	15 March 2024
To:	Hon Casey Costello, Associate Minister of Health		

Purpose of report

1. This briefing provides you with a revised Cabinet paper: Repealing the Therapeutic Products Act.

Revised Cabinet paper

2. On 4 March 2024, you took a paper to Cabinet on progressing work to repeal the Therapeutic Products Act 2023 and modernising regulation of health products [CAB-24-SUB-0065]. Cabinet referred the paper to the Social Outcomes Committee (SOU) for consideration, with a revised paper to be submitted [CAB-24-MIN-0065].

3. The revised Cabinet paper is attached. It proposes a three-pronged approach to address regulation of medicines, medical devices, and natural health products:

   a. repeal the Therapeutic Products Act as soon as possible

   b. explore options for quick opportunities to improve the current system under the Medicines Act and the Dietary Supplements Regulations

   c. develop policy for modern, risk-proportionate, fit for purpose regulation of medicines and medical devices, and for natural health products.

4. Out of scope [redacted]

Next steps

5. You will be meeting with your fellow Associate Minister of Health, Hon David Seymour, on 20 March 2024, to discuss issues covered by the Cabinet paper. We have provided you with an aide-memoire and talking points for this meeting [H2024037138].

6. We recommend you share the revised paper with Minister Seymour ahead of the meeting.

7. We understand the paper will be considered by SOU on 10 April 2024. If your office informs us of any changes to the Cabinet paper by 2 April 2024, we will upload it to the CabNet database by the deadline of 10am on 4 April 2024.

8. As dietary supplements, which are a major group of natural health products, fall within the Food Safety portfolio, you may wish to arrange for Hon Andrew Hoggard, Minister for Food Safety (outside of Cabinet), to attend the Cabinet meeting.

Recommendations

We recommend you:

a)	**Note** that Cabinet has asked for a revised version of your paper on repealing the Therapeutic Products Act 2023 and modernising regulation of health products to be submitted to the Social Outcomes Committee	**Noted**
b)	**Note** that the revised paper is attached	**Noted**
c)	**Note** that you will be meeting with the Associate Minister of Health, Hon David Seymour, on 20 March 2024 to discuss issues covered by the Cabinet paper	**Noted**
d)	**Share** the revised paper with Minister Seymour ahead of the meeting	**Yes / No**
e)	**Inform** Ministry of Health officials of any changes to the paper by close of business on 2 April 2024.	**Yes / No**

Dr Diana Sarfati
Director-General of Health
Te Tumu Whakarae mō te Hauora
Date: 14 March 2024

Hon Casey Costello
Associate Minister of Health
Date:

Document 5

Minister's Notes

Document 7

MANATŪ HAUORA
MINISTRY OF HEALTH

Briefing

Cabinet paper on repealing the Therapeutic Products Act 2023

Date due to MO:	23 April 2024	**Action required by:**	24 April 2024
Security level:	IN CONFIDENCE	**Health Report number:**	H2024039302
To:	Hon Casey Costello, Associate Minister of Health		
Copy to:	Hon Dr Shane Reti, Minister of Health		
Consulted:	Health New Zealand: ☐ Māori Health Authority: ☐		

Contact for telephone discussion

Name	Position	Telephone
Maree Roberts	Deputy Director-General, Strategy, Policy and Legislation	s 9(2)(a)
Tim Vines	Manager, Therapeutics, Strategy, Policy and Legislation	

Minister's office to complete:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Comment:

Document 7

Cabinet paper on repealing the Therapeutic Products Act 2023

Security level:	IN CONFIDENCE	**Date:**	23 April 2024
To:	Hon Casey Costello, Associate Minister of Health		

Purpose of report

1. This briefing provides you with a Cabinet paper on repealing the Therapeutic Products Act 2023, and future direction for therapeutic products policy development. It also provides you with talking points on the paper for your attendance at Cabinet's Social Outcomes Committee (SOU) on 1 May 2024.

Cabinet paper

2. On 4 March 2024, you took a paper to Cabinet on progressing work to repeal the Therapeutic Products Act 2023 (the TPA) and modernising regulation of health products [CAB-24-SUB-0065]. Cabinet referred the paper to SOU for consideration, with a revised paper to be submitted [CAB-24-MIN-0065].

3. We provided you with revised versions of the paper on 15 March 2024 [H2024037132] (the 'March version') and 5 April 2024 [H2024038347] (the 'April version').

4. Ministerial consultation ran from 5 April 2024 to 22 April 2024. In addition to your office circulating the paper to your colleagues, we understand that you discussed the March version of the paper with Associate Minister Hon David Seymour and the April version with Minister Seymour and Hon Dr Shane Reti, Minister of Health.

5. s 9(2)(f)(iv) [redacted]

6. Out of scope [redacted]

7. The paper seeks Cabinet's agreement to issue drafting instructions for a bill to repeal the Therapeutic Products Act (the Repeal Bill), and to develop new policy for therapeutic products. The Repeal Bill will also include a consequential amendment to the Food Act 2014, relating to the expiry date of the Dietary Supplements Regulations 1985.

8. The Minister for Food Safety, Hon Andrew Hoggard, has confirmed that he supports the TPA repeal bill's consequential amendment to the Food Act 2014, which will provide that the Dietary Supplements Regulations will expire on 1 March 2026.

9. Talking points on the paper are provided in the appendix of this briefing.

Next steps

10. The paper is due to be considered by the Cabinet Social Outcomes Committee on 1 May 2024. We will upload the paper to the CabNet database by 10am on Wednesday 24 April 2024.[1]

11. The Dietary Supplements Regulations are the responsibility of the Minister for Food Safety. As Minister Hoggard is outside Cabinet, you may wish to arrange for him to attend SOU on 1 May 2024.

12. Once Cabinet agrees to the recommendations in the paper, we will provide you with:

    a. advice on timelines and high-level elements of the work programme

    b. draft communications material, including a media release.

Recommendations

We recommend you:

a)	**Note** that we provided you with a revised Cabinet paper on repeal of the Therapeutic Products Act and future regulatory reform on 5 April 2024	**Noted**
Out of scope		
c)	**Agree** to the paper being uploaded to the CabNet database by 10am on 24 April 2024, so that it can be considered by the Cabinet Social Outcomes Committee on 1 May 2024	**Yes / No**
d)	**Arrange** for the Minister of Food Safety, Hon Andrew Hoggard, to attend SOU on 1 May 2024	**Yes / No**
e)	**Note** that, once Cabinet has agreed to the recommendations in the paper, we will provide you with advice on timelines and high-level elements of the work programme	**Noted**

Dr Diana Sarfati
Director-General of Health
Te Tumu Whakarae mō te Hauora
Date: 23/4/24

Hon Casey Costello
Associate Minister of Health
Date:

[1] Papers are normally uploaded on Thursdays, but Thursday 25 April 2014 is the Anzac Day public holiday.

Appendix: Talking points on the Cabinet paper on repealing the Therapeutic Products Act

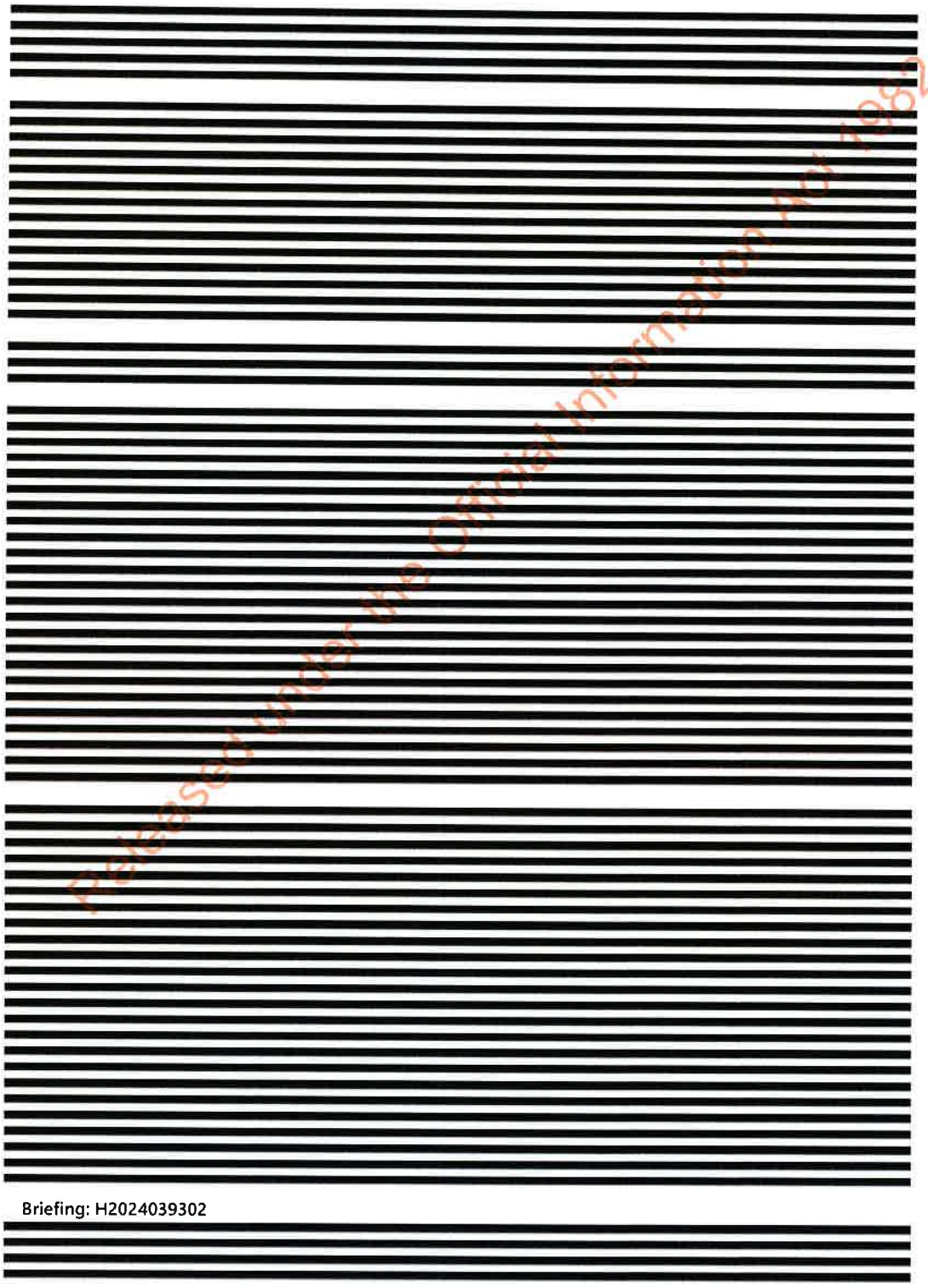
- This paper seeks your agreement to:
  1. draft a bill to repeal the Therapeutic Products Act 2023, and
  2. develop new policy for regulation of medicines, medical devices, and natural health products.
- I propose a four-pronged approach:
  1. a standalone bill to repeal the Therapeutic Products Act this year
  2. targeted improvements by myself and fellow Ministers to the current system under the Medicines Act and Dietary Supplements Regulations
  3. develop modern, risk-proportionate legislation for medicines and medical devices
  4. develop a risk-proportionate approach to natural health products that is supported by the sector.
- Repealing the Therapeutic Products Act is a commitment in both coalition agreements. The Act would have over-regulated natural health products and imposed unnecessary costs on consumers, industry and exporters.
- To deliver on our commitments, I propose that the bill to repeal the Therapeutic Products Act have a category 2 priority on the Legislation Programme. This means it must be passed this year.
- Industry and other stakeholders were very concerned about the Therapeutic Products Act. However, they have also said that we cannot simply revert back to the status quo.
- The current Medicines Act is fundamentally outdated and no longer fit for purpose. Specifically:
  - It is unable to appropriately regulate innovations such as gene therapy and artificial intelligence.
  - It locks our workforce into outdated models of care, by failing to fully recognise the expertise of our nurses and pharmacists.
  - It does not provide us the necessary tools to respond to natural and health emergencies.
- I intend to develop policy for modern, risk proportionate regulation of medicines and medical devices. This will ensure that new medicine approvals are efficient and timely, and that the public is better protected from unsafe products.
- The new system will also support innovation. It will enable modern, risk-proportionate regulation for innovative products such as software as a medical device, artificial intelligence, and gene therapy products. I will work with the Minister of Science, Innovation and Technology to ensure that regulation is modern and future-focused.
- The Dietary Supplements Regulations and other regulation of natural health products is also badly outdated. The industry organisation Natural Health Products New Zealand estimates that New Zealand foregoes around half a billion dollars in export revenue as a result of outdated regulation.

- The Dietary Supplements Regulations are currently set to expire when the Therapeutic Products Act comes into effect. The Therapeutic Products Repeal Bill will therefore make a consequential change to the Food Act, so that the Dietary Supplements Regulations instead expire on 1 March 2026.
- I will work with the Minister of Food Safety and other interested Ministers on a modern solution to replace these regulations, as part of broader work on modern regulation for natural health products.
- I intend to report back to Cabinet by the end of November this year on proposals for future policy direction, including financial implications of these proposals.

ENDS.

Document 7

Minister's Notes



Document 8

MANATŪ HAUORA
MINISTRY OF HEALTH

Briefing

Medical products regulatory reform work programme

Date due to MO:	13 May 2024	**Action required by:**	N/A
Security level:	IN CONFIDENCE	**Health Report number:**	H2024039024
To:	Hon Casey Costello, Associate Minister of Health		
Copy to:	Hon Dr Shane Reti, Minister of Health		
Consulted:	Health New Zealand: ☐ Māori Health Authority: ☐		

Contact for telephone discussion

Name	Position	Telephone
Maree Roberts	Deputy Director-General, Strategy, Policy and Legislation	Out of scope
John McGrath	Director, Priority Projects, Strategy, Policy and Legislation	

Minister's office to complete:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Comment:

Document 8

Medical products regulatory reform work programme

Security level:	IN CONFIDENCE	**Date:**	13 May 2024
To:	Hon Casey Costello, Associate Minister of Health		

Purpose of report

1. This briefing provides you with information on a work programme for regulatory reform for medical products (medicines and medical devices). It is intended to support a meeting and discussion with officials on Friday 17 May 2024.

Summary

2. Cabinet has agreed to a Therapeutic Products Act (TPA) repeal bill, to be passed in 2024. Cabinet also invited you (in consultation with the Hon David Seymour, Associate Minister of Health) to report back before the end of November 2024 on proposals for the future direction for regulation of medicines and medical devices, and for natural health products (NHPs) [CAB-24-MIN-0154].

3. We propose four workstreams, which will support:

   a. repeal of the TPA in 2024

   b. enactment of a Medical Products Bill in this term of parliament, to regulate medicines and medical devices.

   c. development of options for the regulation of natural health products (NHPs) which have the broad support of the NHP sector. We will provide you with advice on this workstream by the end of June 2024

   d. short-term improvements to the current system under the Medicines Act 1981 and other legislation.

4. Timeframes for the workstreams are set out in the body and appendices of this briefing. We invite you to request discussion or further information about any of the elements covered in this briefing.

5. We propose that the scope of the Medical Products Bill cover medicines and medical devices, with the ability to exclude product types from scope where appropriate. We will provide further advice to ensure that definitions do not inadvertently capture non-medical products.

6. s 9(2)(f)(iv) [redacted]

7. [redacted]

Document 8

s 9(2)(f)(iv) [redacted]

8. Some elements of the TPA were not contentious, for example the concepts of controlled activities and market authorisations, which strongly align with international norms. Stakeholder concerns about how these concepts would work in practice will be addressed in development of the Medical Products Bill.

9. s 9(2)(f)(iv) [redacted]

10. s 9(2)(f)(iv) [redacted]

11. We propose that engagement on the Medical Products Bill focus on key stakeholders, and on ensuring that concerns about the TPA are addressed. This approach will help maintain momentum established with the medicines sector during work to develop the TPA.

Recommendations

We recommend you:

a)	**Note** that on 6 May 2024, Cabinet agreed to a Therapeutic Products Act repeal bill, and invited you (in consultation with the Hon David Seymour, Associate Minister of Health) to report back to Cabinet by the end of November 2024 on proposals for future direction for regulation of medicines and medical devices, and for natural health products [CAB-24-MIN-0154]	**Noted**
b)	**Note** that regulatory reform work will consist of four workstreams: 1. a Therapeutic Products Act Repeal Bill 2. a Medical Products Bill to regulate medicines and medical devices 3. development of policy for regulation of natural health products 4. short-term improvements to the current system under the Medicines Act 1981 and other legislation	**Noted**
c)	**Note** the timeframes set out in this briefing for the repeal Bill (paragraph 20) and a new Medical Products Bill (paragraph 26)	**Noted**
d)	**Note** our recommendation for the Medical Products Bill to include medicines and medical devices, with the ability to exclude product types from scope, where appropriate, via secondary legislation	**Noted**

Document 8

i) **Agree** to discuss this briefing with officials on 17 May 2024 **Yes/No**

John McGrath
Director, Priority Projects
Strategy, Policy and Legislation

Hon Casey Costello
Associate Minister of Health
Date:

Document 8

Medical products regulatory reform work programme

Background

12. The regulation of medicines, medical devices and natural health products (NHPs) under the Medicines Act 1981 and other legislation is badly outdated. The Therapeutic Products Act 2023 (the TPA) was an attempt to modernise regulation of these products. However, elements of the TPA were opposed by some industry and other stakeholders, who considered that it would have over-regulated some product types.

13. On 6 May 2024, Cabinet agreed to a standalone bill to repeal the TPA, to be passed in 2024 [CAB-24-MIN-0154]. Cabinet also invited you (in consultation with the Hon David Seymour, Associate Minister of Health) to report back by the end of November 2024 on proposals for future direction for regulation of medicines and medical devices, and for NHPs.

Assumptions

14. The analysis and recommendations in this paper are based on our understanding that the Government wishes to:

    a. enact a bill to regulate medicines and medical devices in this Parliamentary term and will prioritise that bill accordingly

    b. develop a regulatory system for NHPs which is broadly supported by the NHP sector.

15. s 9(2)(f)(iv) [redacted]

Proposed workstreams

16. In order to meet the Government's expectations, we propose four workstreams to run concurrently. This will enable the TPA to be repealed this year, while allowing for robust policy development for future regulation of medicines, medical devices and natural health products.

17. We recommend that reform be progressed via the following workstreams:

    1. A standalone bill to repeal the TPA (the Repeal Bill). Cabinet has agreed that the Repeal Bill will have priority 2 on the legislative programme, meaning it must be passed in 2024 [CAB-24-MIN-0154].

    2. Targeted short-term improvements to the current system under the Medicines Act and other legislation. Out of scope [redacted]

Document 8

Out of scope [redacted] We can provide you with further information on these improvements at your request.

3. Modernising regulation of medical products (medicines and medical devices). A new Medical Products Bill can be introduced to Parliament this term and, subject to Parliament's prioritisation, enacted in 2026. Implementing a new regulatory regime is dependent on a new information technology (IT) system, substantial secondary legislation, and an expanded/adapted Medsafe or new regulator, all of which will need to be operational when the new legislation takes effect. s 9(2)(f)(iv) [redacted]

4. Developing future regulation of NHPs. This includes engaging with the NHP sector, the Ministry for Primary Industries (Food Safety), and the Environmental Protection Agency on options for regulation. We will provide you with advice on this workstream by late June 2024.

18. Putting in place separate regulation for medical products and NHPs will enable development of risk-proportionate regulation for those different types of products. The medical products workstream will progress independently of the NHP workstream, which is likely to require more engagement with key stakeholders due to the range of views within the NHP sector.

Would you like to discuss the proposed workstreams further?	**Yes / No**

Out of scope [redacted]

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Out of scope

[redacted]

Medical Products Bill and regulator

25. Developing a new Medical Products Bill is likely to be complex s 9(2)(f)(iv) [redacted] This complexity will make enactment before the end of the Parliamentary term challenging. If there are any significant delays, it is likely that the Bill will not be passed to this timeframe.

s 9(2)(f)(iv)

[redacted]

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s 9(2)(f)(iv) [redacted]

27. In order to meet these timelines, we propose a targeted consultation approach. Out of scope [redacted]

28. Out of scope [redacted]

29. [redacted]

30. The regulatory system under the Medical Products Bill will need secondary legislation (regulations and rules) for matters which do not appropriately sit in primary legislation. With current resources, we will not be able to focus on secondary legislation work until the Medical Products Bill has been passed s 9(2)(f)(iv) [redacted]

Do you have any questions about the timeframe for developing a new Medical Products Bill?	**Yes / No**

Funding requirements

Out of scope, s 9(2)(f)(iv) [redacted]

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34. Out of scope [redacted]

35. In order to ensure flexible and future-focused regulation, the regulator will need the power to make rules for matters such as specifying international standards for products, and detailed application requirements. Out of scope, s 9(2)(f)(iv) [redacted]

Out of scope, s 9(2)(f)(iv) [redacted]

Proposed approach to engagement

37. The workstreams will require different levels of engagement. In summary:

a. The decision to repeal the TPA has been communicated by you and your Ministerial colleagues since the coalition was formed. Repeal does not involve any further policy decisions, and so public and stakeholder views can be considered via the Select Committee process.

b. We will engage in a targeted way with key stakeholders on the Medical Products Bill and the regulator, this will help ensure that we deliver legislation and a regulator which meets the needs of industry, consumers and the health system.

c. There is a wide range of views across the NHP sector, and identifying a solution for regulation will require engagement with the NHP sector and the general public. We will provide you with advice on NHP engagement by late June 2024.

38. The Medical Products Bill will be the result of 30 years of engagement and policy development on modernising regulation of medical products. We therefore propose that engagement focuses on key stakeholders, and on ensuring that stakeholder and public concerns about the TPA are addressed. To that end, the Ministry will also rely on submissions made to Parliament on the Therapeutic Products Bill. This approach will ensure that momentum from the TPA is retained, and the Medical Products Bill can be enacted in 2026.

39. The key non-government stakeholders for engagement on the Medical Products Bill and the regulator will include health practitioner regulatory and professional bodies, representative groups for the medicine and medical device industries, Māori health providers, and patient and consumer advocacy groups.

40. We will also work closely with Pharmac and Health New Zealand | Te Whatu Ora, and relevant government agencies, including the Ministry for Primary Industries, the Ministry of Foreign Affairs and Trade, the Ministry of Business, Innovation and Employment, the New Zealand Customs Service, and the New Zealand Defence Force. We will also ensure the work aligns with other Government work to support innovation, such as work on a new Gene Technology Regulator.

Do you have any questions about the Ministry's proposed approach to engagement?	**Yes / No**

High-level elements of the Medical Products Bill

41. This section sets out high-level proposals for key aspects of the Medical Products Bill. Your initial decisions on these proposals will enable us to prepare Cabinet papers and, subsequently, drafting instructions for the Parliamentary Counsel Office. The Ministry can also provide more detailed briefings on any of the topics below.

42. s 9(2)(f)(iv) [redacted]

Scope

43. We propose that the Medical Products Bill covers medicines and medical devices, with the ability to exclude specific product types where appropriate. We will provide advice in June 2024 on how to define 'medical product' so that the term does not capture non-medical products which may have a supportive effect on mental or physical health, such as sports equipment.

Would you like to discuss the scope of the Medical Products Bill further, or receive more information about this topic?	**Yes / No**

Purpose

44. Clarifying the purpose of legislation at an early stage helps to guide policy makers during the development of legislation and throughout the legislative and implementation stages. It sets out the overall objective of the legislation.

45. Exact wording of the Bill's purpose will be confirmed during drafting. s 9(2)(f)(iv) [redacted]

Document 8

Out of scope [redacted]

Would you like to discuss the overarching purpose of the Medical Products Bill further, or receive more information about this topic?	**Yes / No**

Principles

48. As with the purpose, agreeing on key regulatory principles early on will ensure clarity and consistency as the Medical Products Bill is developed and implemented.

49. s 9(2)(f)(iv) [redacted]

50.

51.

Would you like to discuss your priorities for the regulatory principles of the Medical Products Bill, or receive more information about this topic?	**Yes / No**

s 9(2)(f)(iv) [redacted]

Document 8

Controlled activities

54. s 9(2)(f)(iv) [redacted]

55. The general concept of controlled activities is common to regulatory systems for medical products in most comparable countries. All activities with medicines that are controlled under the TPA are also controlled under the Medicines Act, generally in the same way. Control of activities recognises that some activities (eg, manufacturing medicines and clinical trials) are dangerous if carried out carelessly, and that control is needed to manage risks to public health.

56. Submitters on the TPA did not oppose the concept of controlled activities. Most concerns (other than those about NHPs) reflected a lack of clarity on what activities would be enabled via licences, permits, and secondary legislation. We will work with stakeholders to ensure that authorisations and the scope of controlled activities are workable and understood. We will provide you with further advice on this matter by the end of June 2024.

Would you like to discuss further, or receive more information about 'controlled activities'?	**Yes / No**

Market authorisations

57. Under the TPA, the general rule was that medicines and medical devices could only be imported, supplied or exported after being issued with a market authorisation by the regulator. This replicates the approach to medicines in the Medicines Act, and extends it to medical devices. The TPA enabled exemptions to this rule for some products, such as personally imported medicines, and unauthorised products used to meet an urgent clinical need. Permits and licences could also be used to allow activities without a market authorisation.

58. Submitters on the TPA did not oppose the concept of market authorisations per se, but did have concerns about how the concept would be applied to particular products or to export-only products. Apart from concerns relating to NHPs, the key concerns related to:

    a. the requirement for mandatory product authorisation for export-only products

    b. whether all medical devices should go through a pre-market evaluation by the regulator before being issued with a market authorisation

    c. whether there would be appropriate authorisation pathways for novel or innovative product types, such as software-as-a-medical-device, or products with unique use-cases, such as radiopharmaceuticals and whole organs

    d. when and how products could be imported and supplied without market authorisation.

Document 8

59. s 9(2)(f)(iv) [redacted]

60. Our advice on market authorisations will reflect Government policy on the use of decisions and approvals by overseas regulators. We will also provide advice on how the Medical Products Bill can enable and support innovation by enabling sponsors to work with the regulator on how the regulatory regime applies to innovative products (eg, AI intended for a therapeutic purpose).

61. If you agree, we will provide you with further detail on market authorisation provisions by the end of June 2024.

Would you like to discuss further, or receive more information about 'market authorisation' and how it can operate in practice?	**Yes / No**

s 9(2)(f)(iv) [redacted]

Document 8

Risks

64. Risks to the works programme relate to short timeframes and resourcing challenges.

65. The Repeal Bill is relatively low risk, as it will be a straightforward bill to prepare, and because repeal has been signalled repeatedly since the coalition agreements were signed. There is some risk that there will be a high volume of submissions on the Repeal Bill, and that this will draw resources from the other workstreams, creating delays.

66. Enacting the Medical Products Bill before the end of the parliamentary term will be challenging. If there are any delays to the timeline, it is likely that the Bill will not be passed before the end of the parliamentary term. This in turn will delay implementation of the new regulatory regime.

67. s 9(2)(f)(iv) [redacted]

68. Out of scope [redacted]

69. s 9(2)(f)(iv) [redacted]

Would you like to discuss how the Ministry will keep you informed of the risks associated with this work programme?	**Yes / No**

Equity

70. Groups which need to use medical products more often are affected more strongly by unsafe, inaccessible or unaffordable products. These groups include older people, Māori and Pacific people (due to higher rates of poor health), disabled people, and people with chronic or rare health conditions. These groups also tend to have lower average incomes, which further increases the impact of higher costs.

Next steps

71. In June 2024, we will provide you with a briefing on policy decisions for the Medical Products Bill, with a focus on market authorisations. In July 2024 we will provide you with a briefing on the form of the regulator and cost recovery.

72. Cabinet decisions will be required in August 2024 in order to support a Budget 2025 bid.

ENDS.

Document 8

Document 8

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Document 9

MANATŪ HAUORA
MINISTRY OF HEALTH

Briefing

Therapeutic Products Act Repeal Bill: Approval to lodge Cabinet paper

Date due to MO:	12 June 2024	**Action required by:**	13 June 2024
Security level:	IN CONFIDENCE	**Health Report number:**	H2024042381
To:	Hon Casey Costello, Associate Minister of Health		
Copy to:	Hon Dr Shane Reti, Minister of Health Hon David Seymour, Associate 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	s 9(2)(a)
Tim Vines	Manager, Therapeutics Strategy, Policy and Legislation	

Minister's office to complete:

☐ Approved ☐ Decline ☐ Noted

☐ Needs change ☐ Seen ☐ Overtaken by events

☐ See Minister's Notes ☐ Withdrawn

Comment:

Document 9

Therapeutic Products Act Repeal Bill: Approval to lodge Cabinet paper

Security level:	IN CONFIDENCE	**Date:**	13 June 2024
To:	Hon Casey Costello, Associate Minister of Health		

Purpose of report

1. This briefing accompanies the Cabinet paper that seeks Cabinet's approval for the introduction of the Therapeutic Products Act Repeal Bill (the Repeal Bill) to Parliament (**appendix one**). It also provides you with talking points on the paper for your attendance at Cabinet's Legislation Committee (LEG) on 20 June 2024 (**appendix two**).

Cabinet Paper seeking approval to introduce the Repeal Bill

2. On 6 May 2024 Cabinet [CAB-24-MIN-0154] agreed to a Bill to:
   a. repeal the Therapeutic Products Act 2023
   b. make consequential amendments to the Food Act 2014 so that the Dietary Supplements Regulations will expire on 1 March 2026, rather than on commencement of the Therapeutic Products Act.
3. Cabinet agreed that the Repeal Bill would have a category two priority (to be passed by the end of the year 2024).
4. A Repeal Bill has now been drafted to give effect to this decision (the latest version of the Repeal Bill is at **appendix three**).

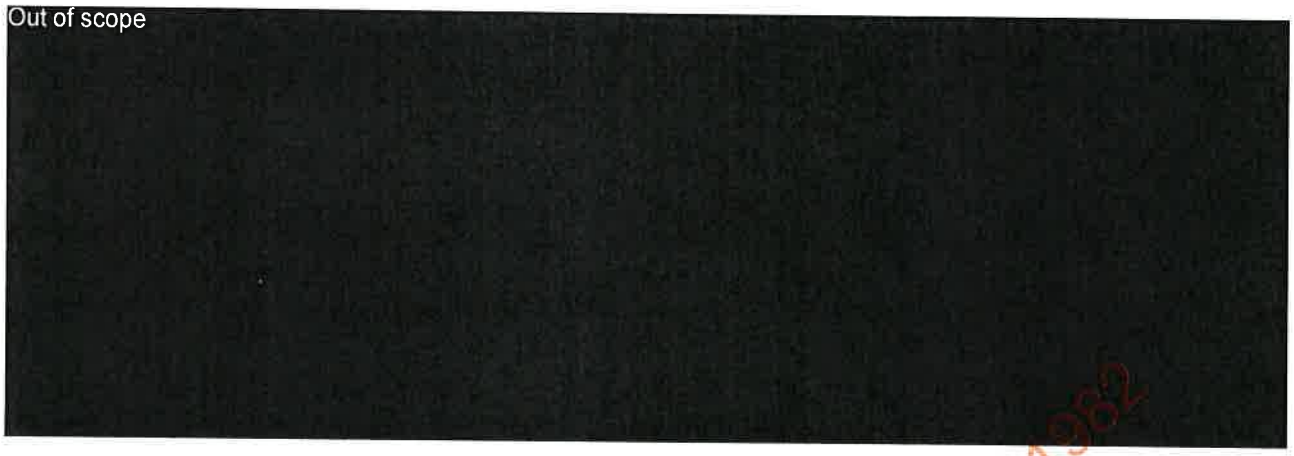
s 9(2)(f)(iv)

5. s 9(2)(f)(iv)

6.

7.

Document 9



Next steps

10. The paper is due to be considered by the LEG on 20 June 2024. With your agreement, we will upload the paper to the CabNet database by 10am on 13 June 2024.[1] The Parliamentary Counsel Office will upload the final Repeal Bill to CabNet and publish the required disclosure statement online (**appendix four**).

11. In anticipation of Cabinet's consideration of the paper and Repeal Bill, we will provide your office with a document pack to support the introduction of the Bill to Parliament. This will include your first reading speech, a copy of the final Repeal Bill, disclosure statement and legislative statement.

12. The Dietary Supplements Regulations 1985 are the responsibility of the Minister for Food Safety. As Minister Hoggard is outside Cabinet, you may wish to arrange for him to attend LEG on 20 June 2024.

13. If LEG agrees to the recommendations in the Cabinet paper, the paper and Repeal Bill can be considered by Cabinet on 24 June 2024. With Cabinet's approval, the Bill can then be introduced to Parliament, and have its first reading in the sitting week of 25 to 27 June 2024. Assuming a select committee process of four months, this will allow the Bill to be passed by the end of November 2024.

14. If the Bill's first reading does not take place in the June sitting week, the next opportunity is 23-25 July. The Bill can still be passed in 2024 on this timetable. However, any further delays would mean the Bill would not be passed this year.

15. The Ministry will provide proposals for new legislation for medicines and medical products, in addition to advice on options for the regulation of natural health products in the coming months. This advice will support several of the Government's priorities, including streamlining the way in which new medicines are approved, and ensuring that regulation supports innovation and economic growth.

Document 9

Out of scope

[redacted]

b) **Agree** to the Cabinet paper being uploaded to the CabNet database by 10am on 13 June 2024, so that it can be considered by the Cabinet's Legislation Committee on 20 June 2024. **Yes / No**

Out of scope

[redacted]

John McGrath
Director, Priority Projects
Strategy, Policy and Legislation
Date: 12/06/2024

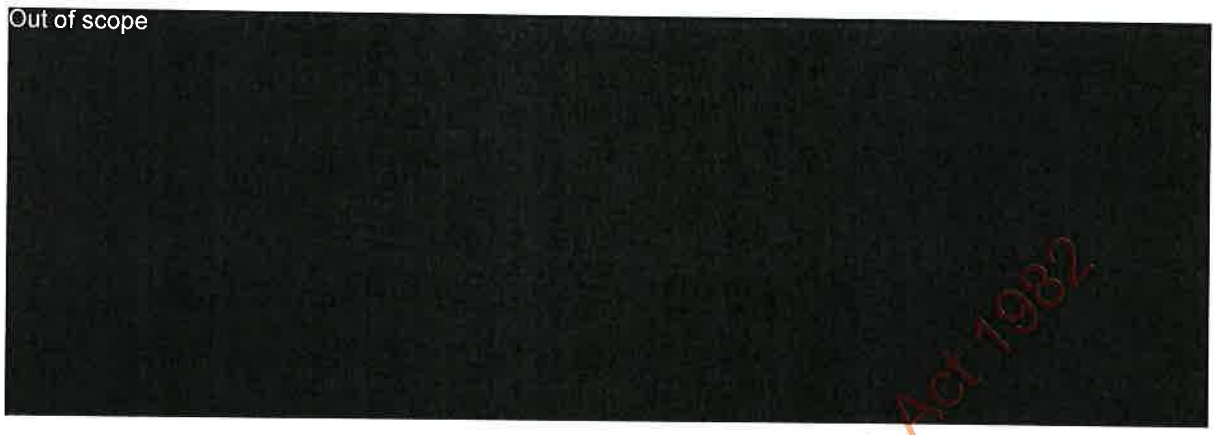
Hon Casey Costello
Associate Minister of Health
Date:

ENDS.

Minister's Notes

Document 9

Appendix two: Talking points on the legislative paper on the introduction of the Therapeutic Products Act Repeal Bill



- In November this year, I will report back to Cabinet on new policy proposals for modern, comprehensive, and fit-for-purpose legislation for medicines, medical devices and natural health products. I will consult with the Hon David Seymour and other interested Ministers as I develop these proposals.