

Briefing

Amending the Therapeutic Products Act Repeal Bill

Date due to MO: 16 September 2024 **Action required by:** 17 September 2024

Security level: IN CONFIDENCE **Health Report number:** H2024049098

To: Hon Casey Costello, Associate Minister of Health

Cc: Hon David Seymour, Associate Minister of Health

Consulted: Health New Zealand:

Contact for telephone discussion

| Name | Position | Telephone |
|----------------------|---|-----------|
| Maree Roberts | Deputy Director-General Strategy Policy and Legislation | s 9(2)(a) |
| Tim Vines | Acting Director, Priority Projects Strategy Policy and Legislation | s 9(2)(a) |

Minister's office to complete:

- | | | |
|---|------------------------------------|--|
| <input type="checkbox"/> Approved | <input type="checkbox"/> Decline | <input type="checkbox"/> Noted |
| <input type="checkbox"/> Needs change | <input type="checkbox"/> Seen | <input type="checkbox"/> Overtaken by events |
| <input type="checkbox"/> See Minister's Notes | <input type="checkbox"/> Withdrawn | |

Comment:

Amending the Therapeutic Products Act Repeal Bill

Security level: IN CONFIDENCE **Date:** 16 September 2024

To: Hon Casey Costello, Associate Minister of Health

Purpose of report

1. This paper seeks your agreement to a draft Cabinet paper that seeks approval to develop an Amendment Paper to the Therapeutic Products Act Repeal Bill (the Repeal Bill) to:
 - a. provide that the Dietary Supplements Regulations 1985 are made pursuant to the Food Act 2014, rather than the Food Act 1981
 - b. provide that the Australia New Zealand Food Standards Code does not apply to dietary supplements.
2. This paper also seeks your agreement to circulate the draft Cabinet paper (**Appendix One**) for agency and Ministerial consultation.

Context

3. In May 2024, Cabinet noted that there would be opportunities to make targeted improvements to the regulation of dietary supplements [CAB-24-MIN-0154]. On 27 June 2024, you and the Hon Andrew Hoggard, Minister for Food Safety, agreed to prioritise improvements to export regulations for dietary supplements.

We propose seeking Cabinet's agreement to amend the current TPA Repeal Bill as a first step to reducing barriers to exporting dietary supplements

4. We recommend you amend the Repeal Bill, via an Amendment Paper, to move the Dietary Supplements Regulations from the Food Act 1981 to the Food Act 2014. This will enable access to provisions within the Food Act 2014 that facilitate exports, such as export exemptions. We also recommend the Amendment Paper provides that the Australia New Zealand Food Standards Code does not apply to dietary supplements to avoid regulatory confusion and maintain the status quo position for dietary supplements with regards to the trans-Tasman regulatory regime for food.
5. **Appendix One** provides a draft Cabinet paper that seeks agreement to prepare the Amendment Paper for introduction after the Repeal Bill is returned from the Health Committee on 1 November 2024.
6. The approach responds to a recommendation by Natural Health Products New Zealand, the industry body for natural health products (including dietary supplements), in their submission on the Repeal Bill.

Engagement with other Ministries and Medsafe

7. The draft Cabinet paper has been developed in conjunction with the Ministry for Primary Industries, who are responsible for the Food Act 2014 and the Dietary Supplement Regulations 1985. Input was received from Medsafe, who have delegated responsibility for administering the Dietary Supplements Regulations 1985.
8. On 29 August 2024, Hon Andrew Hoggard, Minister for Food Safety, and Hon Todd McClay, Minister of Trade requested the Cabinet paper be submitted as a joint (three-way) paper.
9. The draft Cabinet paper foreshadows implementation and resourcing implications for agencies (including Medsafe) in terms of policy development, compliance and verification, issue of export assurances and processing of export exemption applications.
10. Officials will develop further advice on these implications for consideration by Health Ministers and the Minister for Food Safety and the Minister for Trade. Currently, Medsafe is not resourced for administering the Dietary Supplements Regulations. Should Medsafe be responsible for assessing applications for export exemptions, it will require additional resourcing, although some costs would be cost-recovered from industry.
11. If you agree with the draft Cabinet paper, we recommend you consult on it with your Ministerial colleagues, and then seek agreement from the Social Outcomes Committee on 16 October 2024. Due to time constraints, the Ministry will run agency consultation concurrently with Ministerial consultation.
12. If Cabinet agrees, you can introduce the Amendment Paper during the Repeal Bill's Committee of the Whole House stage, which is expected to occur in November 2024.

Recommendations

We recommend you:

- a) **Note** that dietary supplements are regulated under the outdated Dietary Supplements Regulations 1985, which sit under the repealed Food Act 1981, and that this creates barriers for New Zealand exporters **Noted**
- b) **Note** that there is an opportunity to support exporters by amending the Therapeutic Products Act Repeal Bill to move the Dietary Supplements Regulations to the current Food Act 2014 **Noted**
- c) **Note** that the Therapeutic Products Act Repeal Bill can also be amended to clarify that the Australia New Zealand Food Standards Code does not apply to dietary supplements **Noted**
- d) **Note** that moving the Dietary Supplements Regulations to the Food Act 2014 will have implementation and resource implications for Medsafe, given it currently administers the Dietary Supplements Regulations under delegation from the Ministry for Primary Industries **Noted**
- e) **Note** that Hon Andrew Hoggard, the Minister for Food Safety, and Hon Todd McClay, Minister for Trade, have requested that a Cabinet paper to implement recommendations b) and c) be submitted as a joint (three-way) paper **Noted**

- f) **Agree** to consult with your Ministerial colleagues on the draft Cabinet paper **(Appendix One)**, which gives effect to recommendations b) and c) via an Amendment Paper **Yes / No**
- g) **Note** that we recommend you take the attached draft Cabinet paper **(Appendix One)** to the Social Outcomes Committee on 16 October 2024 **Noted**
- h) **Note** that the Ministry will provide you with further advice on the implementation and resourcing implications of progressing targeted improvements to the regulation of exported dietary supplements in October. **Noted**



Maree Roberts
Deputy Director-General
Strategy, Policy and Legislation
Date: 13 September 2024

Hon Casey Costello
Associate Minister of Health
Date:

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Minister's Notes

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Appendix One. Draft Cabinet paper on amending the Therapeutic Products Act Repeal Bill

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In Confidence

Office of the Associate Minister of Health

Office of the Minister for Food Safety

Office of the Minister for Trade

Cabinet Social Outcomes Committee

Amending the Therapeutic Products Act Repeal Bill

Proposal

- 1 This paper seeks agreement to develop an Amendment Paper for the Therapeutic Products Act Repeal Bill (the Repeal Bill) to:
 - 1.1 provide that the Dietary Supplements Regulations 1985 are made pursuant to the Food Act 2014, rather than the Food Act 1981
 - 1.2 provide that the Australia New Zealand Food Standards Code does not apply to dietary supplements, unless provided otherwise in the Dietary Supplements Regulations.

Relation to government priorities

- 2 This proposal supports the Government's target to double export value in 10 years.

New Zealand exporters are held back by outdated regulations

- 3 Dietary supplements, such as vitamin and mineral tablets, are intended to supplement the intake of substances normally derived from food. They are regulated under the Dietary Supplements Regulations 1985.
- 4 The Dietary Supplements Regulations are outdated and not fit for purpose. For example, there is no suitable mechanism to exempt dietary supplements exporters from compliance with domestic labelling requirements when these differ from importing country requirements. This creates barriers for our exporters.
- 5 The Dietary Supplements Regulations sit under the Food Act 1981, which has been repealed. It is possible to amend the Dietary Supplements Regulations as if the Food Act 1981 was still in force. However, this is not good regulatory practice, and risks increasing regulatory confusion and complexity.
- 6 In addition, there is a need to clearly establish the relationship between the Australia New Zealand Food Standards Code and the Dietary Supplements Regulations in New Zealand law.

We have an opportunity to support our exporters

- 7 The Repeal Bill is due to be reported back from the Health Committee on 1 November 2024. The Repeal Bill can be amended to move the Dietary Supplements

Regulations from the repealed Food Act 1981 to the current Food Act 2014, and to clarify that the Australia New Zealand Food Standards Code does not apply to any dietary supplements, unless provided otherwise in the Dietary Supplements Regulations.

- 8 These changes are within scope of the Repeal Bill because it already amends the Food Act 2014 to change the expiry date of the Dietary Supplements Regulations.
- 9 Amending the Food Act 2014, via an Amendment Paper to the Repeal Bill, offers improvements to export settings for dietary supplements compared to the current regime. It would provide regulators (eg, the Ministry for Primary Industries and Medsafe) and the sector access to the full range of tools and provisions within the Food Act 2014. This includes the ability to exempt exported products from domestic composition and labelling requirements, subject to conditions.

The proposed change is part of a wider programme of targeted improvements

- 10 Under the proposed change, the Dietary Supplements Regulations will be brought across to the Food Act 2014 as written. This means the initial impact of the change on the sector will be limited.
- 11 Nonetheless, there will be administrative and resourcing implications for agencies (including Medsafe) in terms of policy development, compliance and verification, issue of export assurances and processing of export exemption applications. Officials will provide further advice on implementing export processes to Health Ministers, the Minister for Food Safety and the Minister for Trade before the end of the year.
- 12 To build on this first step, the Ministry for Primary Industries is working with the Ministry of Health to develop a suite of targeted improvements to facilitate exports of dietary supplements s 9(2)(f)(iv) [REDACTED]
[REDACTED] Progressing the proposed amendment to the Food Act 2014 via the Repeal Bill will remove the need for an additional primary legislative process to achieve these wider changes to the regulation of dietary supplements.

Cost-of-living Implications

- 13 The proposal in this paper has no direct cost-of-living implications.

Financial Implications

- 14 As discussed in paragraph 11, implementing a process to exempt exported dietary supplements on a case-by-case basis will have some resourcing implications for the Ministries of Health and Primary Industries. s 9(2)(f)(ii) [REDACTED]
[REDACTED]
- 15 The Ministry for Primary Industries and the Ministry of Health will work together to establish and implement the case-by-case exemption process. Agencies will be responsible for resourcing their contributions to this work and exemptions will only be issued once the Ministry for Primary Industries has established criteria for the exemptions and other necessary systems are in place.

- 16 Longer term implementation and resourcing implications for regulating dietary supplements will be detailed as part of the development of policy options for targeted improvements to regulating dietary supplements, including a general exemption for exported dietary supplements. Resourcing implications will also be part of future proposals for the regulation of all natural health products, which will include dietary supplements [SOU-24-MIN-0032].

Legislative Implications

- 17 The proposal in this paper requires an Amendment Paper to be drafted.

Impact Analysis

Regulatory Impact Statement

- 18 Cabinet decided to suspend the requirement for Regulatory Impact Statements for decisions relating to 100 Day Plan proposals which solely involve the repeal of legislation. The proposal in this paper is part of the repeal process for the Therapeutic Products Act 2023, and therefore the Ministry for Regulation has confirmed that no Regulatory Impact Statement is required.

Climate Implications of Policy Assessment

- 19 The Climate Implications of Policy Assessment (CIPA) team has been consulted and confirms that the CIPA requirements do not apply to this proposal, as the threshold for significance is not met.

Population Implications

- 20 The proposal in this paper is not expected to impact any population group.

Human Rights

- 21 This policy has no inconsistencies with the New Zealand Bill of Rights Act 1990 or the Human Rights Act 1993.

Use of External Resources

- 22 No external resources were used in development of the policy in this paper.

Consultation

- 23 The Ministry of Health consulted the following agencies: the Ministry for Primary Industries, the Ministry of Business, Innovation and Employment, New Zealand Trade and Enterprise, the Ministry for Regulation, the Ministry for Foreign Affairs and Trade, New Zealand Customs Service, Te Puni Kokiri, the Parliamentary Counsel Office and the Commerce Commission. This paper incorporates feedback that was provided.
- 24 Natural Health Products New Zealand, a key body that represents the dietary supplements industry, is seeking a general exemption for exported dietary supplements. The proposals in this paper will only enable case-by-case exemptions

initially but work is under way on wider reforms. Our proposal is a necessary step to achieving the outcomes industry is seeking.

Communications

- 25 The Associate Minister of Health, Hon Casey Costello, and Minister for Food Safety intend to release a joint media statement and supporting communications when the Health Committee reports back to Parliament on 1 November 2024 on the Repeal Bill. The media release will clarify that this is a necessary step to targeted improvements for dietary supplements, including for export exemptions.

Proactive Release

- 26 The Associate Minister of Health, Hon Casey Costello, intends to proactively release this paper, subject to any necessary redactions as appropriate under the Official Information Act 1982, within 30 days of the Amendment Paper being introduced to Parliament.

Recommendations

The Associate Minister of Health, Hon Casey Costello, the Minister for Food Safety and the Minister for Trade recommend that the Committee:

- 1 note that dietary supplements are regulated under the outdated Dietary Supplements Regulations 1985, which sit under the repealed Food Act 1981, and that this creates barriers for New Zealand exporters
- 2 note that there is an opportunity to support exporters by amending the Therapeutic Products Act Repeal Bill to:
 - 2.1 provide that the Dietary Supplements Regulations are made under the Food Act 2014 rather than the Food Act 1981; and
 - 2.2 provide that the Australia New Zealand Food Standards Code does not apply to dietary supplements, unless provided otherwise in the Dietary Supplements Regulations
- 3 authorise the Associate Minister of Health, Hon Casey Costello, to instruct the Parliamentary Counsel Office to draft an Amendment Paper that gives effect to recommendation 2.1 and 2.2.

Authorised for lodgement

Hon Casey Costello

Associate Minister of Health

Hon Andrew Hoggard

Minister for Food Safety

Hon Todd McClay

Minister for Trade

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Cabinet Social Outcomes Committee

Minute of Decision

This document contains information for the New Zealand Cabinet. It must be treated in confidence and handled in accordance with any security classification, or other endorsement. The information can only be released, including under the Official Information Act 1982, by persons with the appropriate authority.

Amending the Therapeutic Products Act Repeal Bill

Portfolios Trade/ Associate Health (Hon Casey Costello)/ Food Safety

On 23 October 2024, the Cabinet Social Outcomes Committee:

- 1 **noted** that dietary supplements are regulated under the outdated Dietary Supplements Regulations 1985, which sit under the repealed Food Act 1981, which creates barriers for New Zealand exporters;
- 2 **noted** that there is an opportunity to support exporters by amending the Therapeutic Products Act Repeal Bill to:
 - 2.1 provide that the Dietary Supplements Regulations are made under the Food Act 2014 rather than the Food Act 1981; and
 - 2.2 provide that the Australia New Zealand Food Standards Code does not apply to dietary supplements, unless provided otherwise in the Dietary Supplements Regulations;
- 3 **invited** the Associate Minister of Health (Hon Casey Costello) to instruct the Parliamentary Counsel Office to draft an Amendment Paper that gives effect to the amendments in paragraph 2.

Jenny Vickers
Committee Secretary

Present:

Rt Hon Winston Peters
Hon David Seymour
Hon Nicola Willis (Chair)
Hon Erica Stanford
Hon Paul Goldsmith
Hon Louise Upston
Hon Mark Mitchell
Hon Tama Potaka
Hon Matt Doocoy
Hon Melissa Lee
Hon Nicole McKee
Hon Casey Costello
Hon Penny Simmonds
Hon Nicola Grigg
Hon Karen Chhour

Officials present from:

Office of the Prime Minister
Officials Committee for SOU



Cabinet

Minute of Decision

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Report of the Cabinet Social Outcomes Committee: Period Ended 25 October 2024

On 29 October 2024, Cabinet made the following decisions on the work of the Cabinet Social Outcomes Committee for the period ended 25 October 2024:

Out of scope



SOU-24-MIN-0133

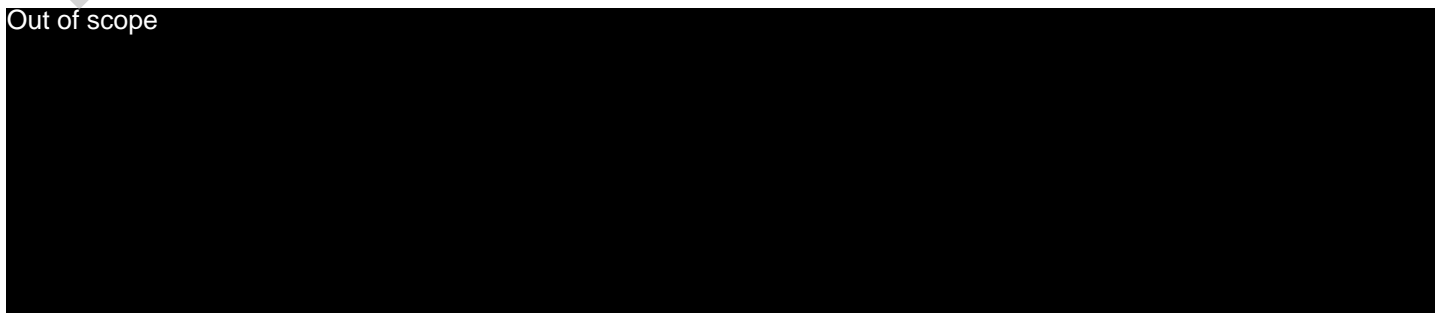
Amending the Therapeutic Products Act Repeal Bill

CONFIRMED


Portfolios: Trade / Associate Health (Hon Casey Costello)

/ Food Safety

Out of scope



Out of scope



Rachel Hayward
Secretary of the Cabinet

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Office of the Associate Minister of Health

Office of the Minister for Food Safety

Office of the Minister for Trade

Cabinet Legislation Committee

Amending the Therapeutic Products Act Repeal Bill

Proposal

- 1 This paper seeks approval for the introduction of an Amendment Paper to the Therapeutic Products Act Repeal Bill (the Bill).

Policy

- 2 On 29 October 2024, Cabinet agreed to an Amendment Paper to the Bill to:
 - 2.1 provide that the Dietary Supplements Regulations 1985 are made pursuant to the Food Act 2014, rather than the Food Act 1981
 - 2.2 provide that the Australia New Zealand Food Standards Code does not apply to dietary supplements, unless provided otherwise in the Dietary Supplements Regulations [CAB-24-MIN-0412].
- 3 The attached Amendment Paper gives effect to Cabinet's agreement.

A decision is required on an additional consequential amendment

- 4 The need for an additional consequential amendment has been identified through the drafting of the Amendment Paper.
- 5 Section 391 of the Food Act 2014 only provides the power to stipulate 'infringement offences' under regulations and not offences. The offences listed in Part 3 of the current Dietary Supplement Regulations 1985 (Regulations) are not 'infringement offences' and, as such, they are inconsistent with section 391 of the Food Act 2014. In any event, the Ministry for Primary Industries advises that the offences in the current Regulations would be difficult to reconcile with the offences in the Food Act 2014.
- 6 We seek Cabinet approval to revoke Part 3 of the Regulations ('Offences and Penalty') and rely, instead, on the offences under the Food Act 2014, for example, section 244 which makes it an offence to breach a regulation.
- 7 This does not constitute a change in policy as the policy is to bring the Regulations under the modern Food Act. When the 1981 Food Act was repealed, and the Regulations were saved by the Food Act 2014, the offences and penalties made under the Food Act 2014 applied to dietary supplements.

Impact analysis

Regulatory Impact Statement

- 8 Cabinet decided to suspend the requirement for Regulatory Impact Statements for decisions relating to 100 Day Plan proposals which solely involve the repeal of legislation. The proposal in this paper is part of the repeal process for the Therapeutic Products Act 2023, and therefore the Ministry for Regulation has confirmed that no regulatory impact statement is required.

Climate Implications of Policy Assessment

- 9 The Climate Implications of Policy Assessment (CIPA) team has been consulted and confirms that the CIPA requirements do not apply to this proposal, as the threshold for significance is not met.

Compliance

Human Rights

- 10 This Bill is consistent with the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993.

Disclosure Statement

- 11 An updated disclosure statement has been prepared and is attached to the paper.

Consultation

- 12 The Ministry of Health consulted the following agencies: the Ministry for Foreign Affairs and Trade; the Ministry for Primary Industries; the Parliamentary Counsel Office and New Zealand Trade and Enterprise. Having been consulted on the previous policy paper [CAB-24-MIN-0412] the Ministry notified the following agencies: the Treasury; the Ministry of Business, Innovation and Employment; the Ministry for Regulation; Te Puni Kōkiri; the New Zealand Customs Service and the Commerce Commission. The Department of the Prime Minister and Cabinet was informed.
- 13 The offence and penalty vetting team within the Ministry of Justice were informed of the proposal to revoke Part 3 of the Regulations.

Binding on the Crown

- 14 The primary Act is binding on the Crown.

Allocation of decision-making powers

- 15 This Amendment Paper does not allocate decision-making powers between the executive, the courts, and the tribunals.

Other instruments

- 16 The proposed Amendment Paper does not include a provision empowering the making of other instruments that are deemed to be legislative instruments or disallowable instruments.

Commencement of legislation

- 17 The Bill that this paper amends will come into force on the day after the Royal assent.

Parliamentary stages

- 18 The Bill was reported back by the Health Committee on 29 October 2024. The Amendment Paper will be introduced in the Committee of the whole House.

Proactive Release

- 19 The Associate Minister of Health, Hon Casey Costello, intends to proactively release this paper, subject to any necessary redactions as appropriate under the Official Information Act 1982, within 30 days of the Amendment Paper being introduced to Parliament.

Recommendations

We recommend that the Cabinet Legislation Committee:

- 1 **note** that the Therapeutic Products Act Repeal Bill holds a category 2 priority on the 2024 Legislation Programme (must be passed by the end of 2024);
- 2 **note** Cabinet agreed to amend the Therapeutic Products Act Repeal Bill CAB-24-MIN-0412 to;
 - 2.1 provide that the Dietary Supplements Regulations 1985 are made pursuant to the Food Act 2014, rather than the Food Act 1981
 - 2.2 provide that the Australia New Zealand Food Standards Code does not apply to dietary supplements, unless provided otherwise in the Dietary Supplements Regulations;
- 3 **note** that the attached Amendment Paper gives effect to the policy decision in recommendation 2;
- 4 **approve**, as a further consequential amendment, the revocation of Part 3 (Offences and penalty) of the Dietary Supplements Regulations 1985 as part of the Amendment Paper.

- 5 **approve** the Amendment Paper to the Therapeutic Products Act Repeal Bill for introduction during the Committee of the whole House debate, subject to the final approval of the Government caucus and sufficient support in the House of Representatives.

Authorised for lodgement

Hon Casey Costello

Associate Minister of Health

Hon Andrew Hoggard

Minister for Food Safety

Hon Todd McClay

Minister for Trade

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Cabinet Legislation Committee

Minute of Decision

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Therapeutic Products Act Repeal Bill: Amendment Paper

Portfolio Trade / Associate Health (Hon Casey Costello) / Food Safety

On 5 December 2024, the Cabinet Legislation Committee:

- 1 **noted** that the Therapeutic Products Act Repeal Bill holds a category 2 priority on the 2024 Legislation Programme (must be passed by the end of 2024);
 - 2 **noted** that in October 2024, the Cabinet Social Outcomes Committee invited the Associate Minister of Health (Hon Casey Costello) to issue drafting instructions for an Amendment paper to the Therapeutic Products Act Repeal Bill to provide that:
 - 2.1 the Dietary Supplements Regulations 1985 are made pursuant to the Food Act 2014, rather than the Food Act 1981;
 - 2.2 the Australia New Zealand Food Standards Code does not apply to dietary supplements, unless provided otherwise in the Dietary Supplements Regulations;
- [SOU-24-MIN-0133]
- 3 **noted** that the Amendment Paper, attached under LEG-24-SUB-0262, gives effect to the above decisions;
 - 4 **approved**, as a further consequential amendment, the revocation of Part 3 (Offences and Penalty) of the Dietary Supplements Regulations 1985, to be included in the Amendment Paper;
 - 5 **approved** the Amendment Paper to the Therapeutic Products Act Repeal Bill [PCO 26065-2/9.0] for release.

Tom Kelly
Committee Secretary

Attendance: (See over)

Present:

Hon Chris Bishop (Chair)
Hon Simeon Brown
Hon Shane Jones
Hon Brooke van Velden
Hon Casey Costello
Hon Nicole McKee
Hon Simon Watts
Hon Nicola Grigg
Hon Andrew Bayly
Hon Scott Simpson, MP
Todd Stephenson, MP

Officials present from:

Officials Committee for LEG
Leader of the House's Office

PROACTIVELY RELEASED



Cabinet

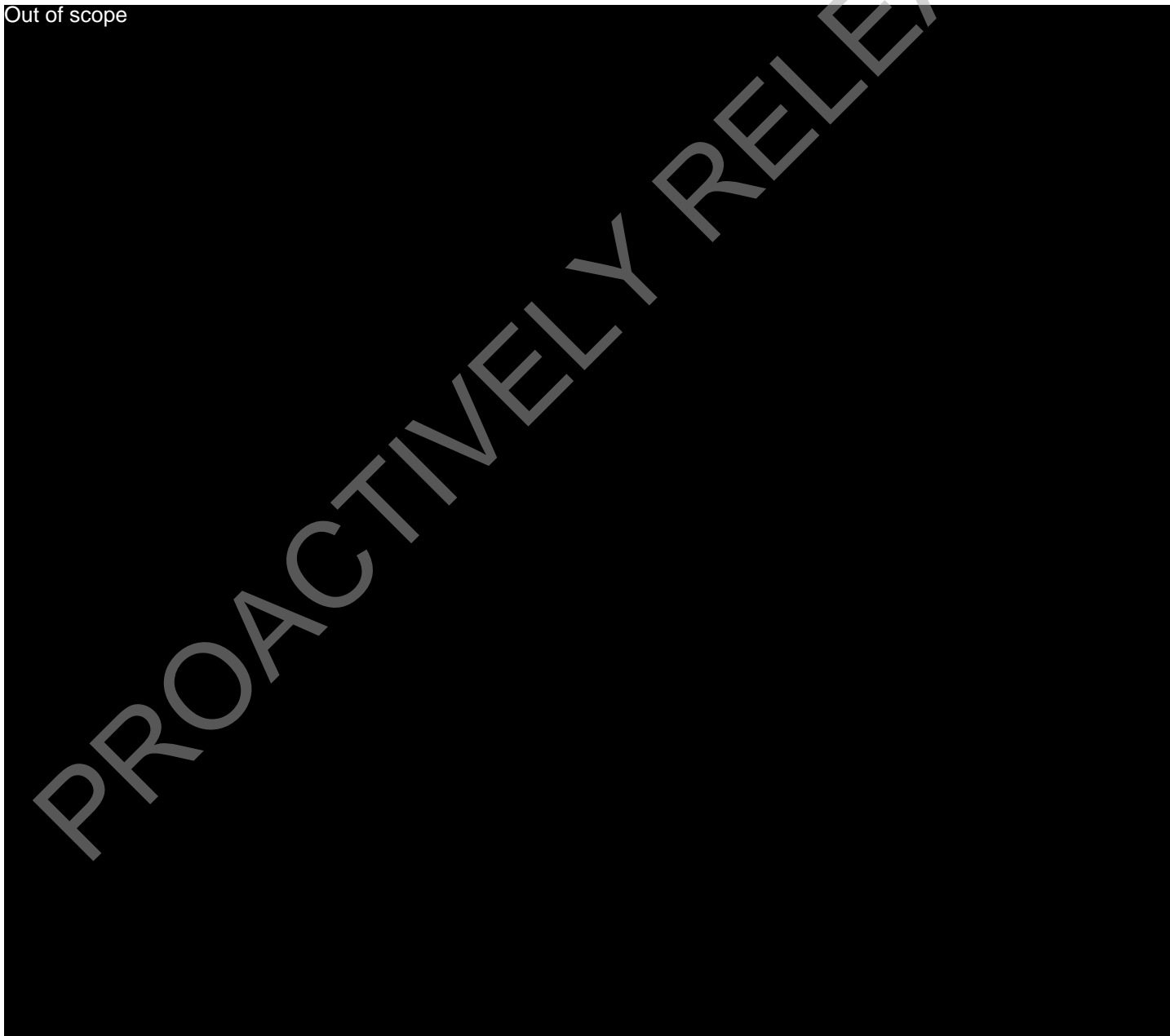
Minute of Decision

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Report of the Cabinet Legislation Committee: Period Ended 6 December 2024

On 9 December 2024, Cabinet made the following decisions on the work of the Cabinet Legislation Committee for the period ended 6 December 2024:

Out of scope



Out of scope



LEG-24-MIN-0262

**Therapeutic Products Act Repeal Bill: Amendment
Paper**

CONFIRMED

Portfolios: Trade / Associate Health (Hon Casey Costello)
/ Food Safety

Rachel Hayward
Secretary of the Cabinet

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