

Departmental Disclosure Statement

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

It identifies:

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

This disclosure statement was prepared by the Ministry of Health.

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

11 June 2024

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Part One: General Policy Statement

The main purpose of the Therapeutic Products Act Repeal Bill (TPA Repeal Bill) is to repeal the Therapeutic Products Act 2023 (TPA). The Bill delivers on the Government's commitment to repeal the TPA.

The TPA, which has a commencement date of 1 September 2026, is intended to replace the Medicines Act 1981 and the Dietary Supplements Regulations 1985. The Government intends to develop new proposals for medicines, medical devices, and natural health products. In the interim, the Medicines Act 1981 and the Dietary Supplements Regulations 1985 will continue in force.

The Bill reverses consequential amendments to the Food Act 2014 made by the TPA and reverts the expiry date of the Dietary Supplements Regulations 1985 to 1 March 2026.

As most provisions of the TPA have not commenced, no transitional or savings provisions are required for this Bill.

Part Two: Background Material and Policy Information

Published reviews or evaluations

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| 2.1. Are there any publicly available inquiry, review or evaluation reports that have informed, or are relevant to, the policy to be given effect by this Bill? | NO |
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Relevant international treaties

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| 2.2. Does this Bill seek to give effect to New Zealand action in relation to an international treaty? | NO |
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| 2.2.1. If so, was a National Interest Analysis report prepared to inform a Parliamentary examination of the proposed New Zealand action in relation to the treaty? | NO |
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Regulatory impact analysis

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| 2.3. Were any regulatory impact statements provided to inform the policy decisions that led to this Bill? | NO |
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| 2.3.1. If so, did the RIA Team in the Treasury provide an independent opinion on the quality of any of these regulatory impact statements? | NO |
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| 2.3.2. Are there aspects of the policy to be given effect by this Bill that were not addressed by, or that now vary materially from, the policy options analysed in these regulatory impact statements? | NO |
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Extent of impact analysis available

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| 2.4. Has further impact analysis become available for any aspects of the policy to be given effect by this Bill? | NO |
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| 2.5. For the policy to be given effect by this Bill, is there analysis available on: | |
| (a) the size of the potential costs and benefits? | NO |
| (b) the potential for any group of persons to suffer a substantial unavoidable loss of income or wealth? | NO |

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| 2.6. For the policy to be given effect by this Bill, are the potential costs or benefits likely to be impacted by: | |
| (a) the level of effective compliance or non-compliance with applicable obligations or standards? | NO |
| (b) the nature and level of regulator effort put into encouraging or securing compliance? | NO |

Part Three: Testing of Legislative Content

Consistency with New Zealand's international obligations

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

It is considered this Bill is consistent with the relevant international standards and obligations.

Consistency with the government's Treaty of Waitangi obligations

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

As the provisions of the Therapeutic Products Act 2023 had not commenced, its repeal by this Bill will not change the existing policy and regulatory settings for therapeutics products. Consequently, this Bill has no impacts that are inconsistent with the principles of the Treaty of Waitangi. Repealing the Therapeutic Products Act 2023 will address concerns from some Māori and rongoā Māori practitioners that the Therapeutic Products Act 2023 would have permitted the Crown to regulate traditional Māori healing practices in a manner not consistent with the principles of the Treaty of Waitangi.

Consistency with the New Zealand Bill of Rights Act 1990

3.3. Has advice been provided to the Attorney-General on whether any provisions of this Bill appear to limit any of the rights and freedoms affirmed in the New Zealand Bill of Rights Act 1990?

NO

Offences, penalties and court jurisdictions

3.4. Does this Bill create, amend, or remove:

(a) offences or penalties (including infringement offences or penalties and civil pecuniary penalty regimes)?

NO

(b) the jurisdiction of a court or tribunal (including rights to judicial review or rights of appeal)?

NO

3.4.1. Was the Ministry of Justice consulted about these provisions?

NO

Privacy issues

3.5. Does this Bill create, amend or remove any provisions relating to the collection, storage, access to, correction of, use or disclosure of personal information?

NO

3.5.1. Was the Privacy Commissioner consulted about these provisions?

NO

External consultation

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| 3.6. Has there been any external consultation on the policy to be given effect by this Bill, or on a draft of this Bill? | NO |
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Other testing of proposals

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| 3.7. Have the policy details to be given effect by this Bill been otherwise tested or assessed in any way to ensure the Bill's provisions are workable and complete? | NO |
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Part Four: Significant Legislative Features

Compulsory acquisition of private property

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| 4.1. Does this Bill contain any provisions that could result in the compulsory acquisition of private property? | NO |
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Charges in the nature of a tax

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| 4.2. Does this Bill create or amend a power to impose a fee, levy or charge in the nature of a tax? | NO |
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Retrospective effect

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| 4.3. Does this Bill affect rights, freedoms, or impose obligations, retrospectively? | NO |
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Strict liability or reversal of the usual burden of proof for offences

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| 4.4. Does this Bill: | |
| (a) create or amend a strict or absolute liability offence? | NO |
| (b) reverse or modify the usual burden of proof for an offence or a civil pecuniary penalty proceeding? | NO |

Civil or criminal immunity

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| 4.5. Does this Bill create or amend a civil or criminal immunity for any person? | NO |
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Significant decision-making powers

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| 4.6. Does this Bill create or amend a decision-making power to make a determination about a person's rights, obligations, or interests protected or recognised by law, and that could have a significant impact on those rights, obligations, or interests? | NO |
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Powers to make delegated legislation

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| 4.7. Does this Bill create or amend a power to make delegated legislation that could amend an Act, define the meaning of a term in an Act, or grant an exemption from an Act or delegated legislation? | NO |
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| 4.8. Does this Bill create or amend any other powers to make delegated legislation? | NO |
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Any other unusual provisions or features

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| 4.9. Does this Bill contain any provisions (other than those noted above) that are unusual or call for special comment? | NO |
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