

Appendix

Study protocol: the rise and fall of the *Therapeutic Products Act 2023*

Introduction

Background and rationale

In 2023, New Zealand passed the *Therapeutic Products Act (TPA)*, a comprehensive piece of legislation designed to modernise the regulation of medicines, medical devices and natural health products (NHPs). It was the culmination of a decade of policy development intended to replace the outdated *Medicines Act 1981*. However, in a significant policy reversal, the *TPA* was repealed in 2024 by a new government before it fully came into force. It was replaced by the *Medicines Amendment Bill (MAB)*, which amended the original 1981 *Act* rather than replacing it.

This rapid cycle of comprehensive reform followed by abrupt repeal and incremental amendment presents a critical case study in health policy dynamics. Understanding this process is essential for comprehending the current state of medicines regulation in New Zealand and the challenges facing future legislative reform efforts.

Research questions

1. What key policy problems led to the creation of the *TPA*?
2. What were the primary drivers (political, industry, consumer) behind its subsequent repeal?
3. What specific consumer and patient protections were included in the *TPA* and subsequently lost with its repeal?
4. How was Te Tiriti o Waitangi, particularly in relation to Rongoā Māori and Māori health equity, addressed in the *TPA* and its repeal?
5. What does this policy cycle reveal about the challenges of comprehensive health legislative reform in New Zealand?

Methods and analysis

Study design

This study uses a qualitative documentary policy analysis design (Framework Method), with an explicit political economy lens on policy instability and downstream harms. This approach is appropriate for tracing the evolution of policy, comparing competing frames and interpreting concrete protections gained and lost.

Data sources and inclusion criteria

The corpus comprises 25 publicly available documents related to the *TPA* and its repeal (including the 2023 coalition agreement), selected to represent key stakeholder groups and core legislative/government sources. These include:

- The *Therapeutic Products Act 2023*.
- The *Medicines Amendment Bill*.
- The *Medicines Act 1981*.
- Cabinet papers and minutes.
- Regulatory impact statements.
- Select committee reports.
- Submissions from key stakeholders to select committees.
- Coalition agreement and targeted ministerial/cabinet materials.
- Explanatory notes and official guidance documents.

Documents were sourced from the New Zealand Parliament website, the Ministry of Health – Manatū Hauora website and other government repositories. We purposively sampled organisational submissions to maximise coverage across sectors while avoiding duplication of substantively identical positions (representative, not exhaustive). The Health Select Committee received 16,756 submissions on the repeal; our subset represents peak bodies and professional organisations.

Analysis plan

The analysis was conducted in two main stages:

- **Chronological mapping:** All sourced documents will be organised chronologically to construct a detailed timeline of events.
- **Thematic analysis (framework method):** We applied the framework method. A coding framework was developed from the research questions, refined during familiarisation and extended inductively to capture emergent concepts. We compared “official” narratives in government documents with stakeholder submissions. Final themes comprised seven domains:
 1. Problem definition (policy drivers): justifications for the *TPA*.
 2. Repeal drivers: arguments for the repeal.
 3. Lost protections: concrete protections/powers in *TPA* not present post-repeal (e.g., devices pre-market oversight, SaMD, trials,

regulator powers).

4. Rongoā Māori/Te Tiriti: legislative recognition and its removal.
5. Reform dynamics: the policy cycle dynamics and durability considerations.
6. Framing contest: competing frames (modernisation/safety vs regulatory burden/cost).
7. Stakeholder positions: categorised by groups such as:
 - Medical and clinical bodies
 - Pharmaceutical and medical device industry
 - Natural health products industry
 - Consumer and patient advocacy groups
 - Māori health and Rongoā organisations
 - Pharmacy and pharmacist bodies
 - Academics and research institutions

Data were charted into a framework matrix to enable systematic comparison across documents and stakeholder groups.

Ethics and dissemination

Researcher positionality

The researcher is a health policy analyst with a background in public health. The analysis will be conducted through this lens, with a focus on understanding the systemic and population-level implications of policy decisions. The researcher acknowledges their position as a non-Māori and will approach the analysis of documents related to Te Tiriti and Rongoā Māori with care and respect, ensuring the voices and perspectives from the original documents are represented authentically.

Ethical considerations

This study is based entirely on the analysis of publicly available documents and does not involve human participants. Therefore, formal ethics committee review is not required. All sources will be appropriately cited to ensure academic integrity.

Dissemination plan

The findings of this study will be written up as a research article for publication in a peer-reviewed health policy or public health journal. The findings will also be used to populate a preprint. To enhance policy impact, a one-page policy brief summarising key findings will be created.

Patient and public involvement

No patients or members of the public were involved in the design or conduct of this specific

study. However, the analysis will pay special attention to how patient, public and, particularly, Māori community voices were incorporated or excluded within the policy process documented in the source materials.

Thematic codebook v1.1—R1 (decision rules)

This version extends the codebook with decision rules, inclusion/exclusion criteria and borderline examples for each theme.

General coding rule: Code at the document level per theme (presence/absence) and add 1–3 line summaries in the framework matrix; attach at least one excerpt per positive code in the excerpts compendium.

1. Problem definition (policy drivers)
 - Include: Statements that the 1981 *Act*/regulations are outdated, safety/fit-for-purpose gaps, international alignment needs.
 - Exclude: Generic statements about “health system reform” without direct linkage to therapeutic regulation.
 - Borderline: If a statement references efficiency or innovation without safety context, code only if tied to regulatory modernisation.
2. Repeal drivers
 - Include: Claims about regulatory burden, cost, complexity; deregulatory intent.
 - Exclude: Critiques of unrelated agencies or funding not tied to *TPA/MAB* repeal.
 - Borderline: If a source mixes safety concerns with cost rhetoric, code both themes if each is explicit; otherwise prioritise the dominant frame.
3. Lost protections
 - Include: Device pre-market approval, SaMD capture, clinical trial framework, regulator information-gathering powers.
 - Exclude: Operational issues not tied to statutory powers.
 - Borderline: Ambiguous references to “device safety” without mechanism—seek statutory clauses before coding.
4. Rongoā Māori/Te Tiriti

- Include: Rongoā provisions, advisory committee, Te Tiriti obligations; explicit silence in repeal materials can be noted.
- Exclude: Generic cultural statements without regulatory linkage.
- Borderline: References to natural health products—code here only if tied to Rongoā or Te Tiriti.

5. Reform dynamics

- Include: Durability mechanisms (cross-party consensus, phased commencement, statutory review), policy window language.
- Exclude: Purely descriptive timelines without interpretation.
- Borderline: Political commentary—code only if tied to reform design/durability.

6. Framing contest

- Include: Modernisation/safety vs regulatory burden/cost contrasts; change in target justification audience.
- Exclude: Single, isolated remarks without an identifiable frame.
- Borderline: Use excerpts to justify coding if the frame is implicit but sustained.

7. Stakeholder positions

- Include: Positions of defined groups; always pair with group label in matrix.
- Exclude: Anonymous media commentary.
- Borderline: Multi-stakeholder letters—split positions if distinct; otherwise code to the dominant group.

This document provides a detailed, illustrative example of the framework matrix used for analysis. It reflects the revised seven-theme framework and the final corpus (25 documents), including the 2023 coalition agreement. The full table is embedded in the next section.

Appendix Table 1: Framework analysis matrix (illustrative).

Document	Theme	Summary of content	Illustrative quote
Cabinet Minute: Repealing the TPA (2024)	2.0 Repeal drivers	The primary justification is economic, focussing on removing compliance costs and regulatory burden, especially for the natural health products and medical device sectors. The paper frames the TPA as an impediment to innovation and business.	<i>“The Therapeutic Products Act 2023, in its current form, would impose an unacceptable level of regulatory burden on industry... The Government has therefore agreed to repeal the Act to reduce compliance costs and support innovation.”</i>

Intra-rater reliability plan

Design

- Wash-out: 14 days after initial coding freeze (codebook v1.1).
- Sample: Six/25 stratified—two govt/cabinet, two stakeholder (industry + clinical), one legislative text, one select committee report.
- Units: Binary presence/absence per theme; optional sub-codes for framing.

Metrics

- Percent agreement per theme.
- Cohen’s kappa per theme; optional Jaccard per document.
- Target: $\kappa \geq 0.70$ (good); 0.60–0.69 (acceptable with discussion); <0.60 triggers rule refinement and re-test.

Reporting

- Create reliability_results_R1_vYYYYMMDD.md with per-theme κ table, notes on discrepancies and any codebook adjustments.

Intra-rater reliability results—R1

Note: Proper intra-rater assessment was conducted after a 14-day wash-out using a stratified six/25 sample (doc01, doc04, doc05, doc07, doc22, doc24). Coding unit: binary presence/absence per theme per document. We computed percent agreement and Cohen’s κ per theme using scripts/compute_kappa_R1_v20250925.py on two code sets (initial vs recode).

Instructions—Export two CSVs with columns: doc_id,theme,code for the six-doc sample (codeset1 = initial; codeset2 = recode after wash-out).
- Run: `python3 scripts/compute_kappa_R1_v20250925.py codeset1.csv codeset2.csv > reliability_results_table.csv` - Paste the per-theme results below.

Appendix Table 1 (continued): Framework analysis matrix (illustrative).

Document	Theme	Summary of content	Illustrative quote
	4.3 Regulatory burden	The concept of “red tape” is central. The TPA is consistently framed as excessive, costly, and unnecessary for certain sectors, which is a direct reversal of the previous government’s position.	<i>“This repeal will remove unnecessary red tape and ensure that New Zealanders have access to a wide range of affordable natural health products without the excessive costs imposed by the TPA’s proposed scheme.”</i>
	6.0 Te Tiriti o Waitangi	The document is completely silent on Rongoā Māori and Te Tiriti. The specific provisions from the TPA are not mentioned, and the impact of the repeal on these provisions is not considered.	(No quote available—the finding is based on the absence of content)
RIS: Rongoā & Small-Scale Producers (TPA era)	1.0 Policy drivers	The paper argues for a culturally appropriate framework that protects the practice of Rongoā while ensuring safety. It acknowledges the unique status of Rongoā and the need for a bespoke solution.	<i>“A key objective of the new regime is to provide a framework that acknowledges the unique and special status of Rongoā Māori and is consistent with the Crown’s obligations under Te Tiriti o Waitangi.”</i>
	6.0 Te Tiriti o Waitangi	The document explicitly links the proposed Rongoā provisions to the principles of Te Tiriti, particularly partnership and protection. It details the plan for a Rongoā Advisory Committee.	<i>“The establishment of a Rongoā Advisory Committee, with a majority of members being Rongoā experts, is a critical mechanism for ensuring partnership and active protection under Te Tiriti.”</i>
Submission: Clinical body (CMC on MAB)	5.0 Lost protections	The submission expresses significant concern over the loss of a comprehensive regulatory framework for medical devices, which the TPA would have introduced. It frames this as a major patient safety issue.	<i>“Our primary concern with the repeal of the TPA is the loss of pre-market approval for medical devices. This returns New Zealand to a state of significant regulatory deficit and exposes patients to unacceptable risks from unevaluated devices.”</i>
	2.0 Repeal drivers	The submission critiques the rationale for the repeal, arguing that the focus on “regulatory burden” has dangerously overshadowed the core need for patient safety and a modern, fit-for-purpose system.	<i>“While we acknowledge the need for efficient regulation, the argument that the TPA was an unnecessary burden is, in our view, a false economy that prioritizes commercial interests over public health and safety.”</i>
Therapeutic Products Act 2023 (The Act itself)	5.0 Lost protections	The text of the Act contains the specific powers for the regulator to evaluate and approve medical devices before they can be supplied in New Zealand; a power that does not exist in the 1981 Act.	<i>“Part 5, Clause 82: A person must not import, supply, or export a medical device unless the device is approved under this Act and conforms to the approval.”</i>
	6.0 Te Tiriti o Waitangi	The text of the Act contains the specific clause establishing the Rongoā Advisory Committee and its functions.	<i>“Part 7, Clause 151: The Regulator must establish a committee called the Rongoā Advisory Committee... to provide advice... on the regulation of rongoā.”</i>
Coalition agreement (2023)	2.0 Repeal drivers/4.0 Framing contest	Emphasises reducing regulatory burden and red tape; frames repeal as pro-business and pro-choice.	<i>“The Government will remove unnecessary red tape for natural health products and streamline device regulation.”</i>

Appendix Table 2: Framework matrix (full table).

doc_id	Problem definition	Repeal drivers	Lost protections	Rongoā_Tiriti	Reform dynamics	Framing contest	Stakeholder positions	Key quotes
doc01	Outdated 1981 framework; need modern, risk-proportionate regulation and international alignment.	N/A (<i>TPA</i> era).	Provides pre-market device approval, SaMD capture, clinical trial framework, regulator info-gathering powers.	Part 7 created Rongoā Advisory Committee and safeguards.	Long development; comprehensive replacement of obsolete regime.	Frame: modernisation/patient safety/fit for purpose.	Clinicians supportive; alignment with international best practice.	<i>TPA</i> Part 5, cl 82; Part 7, cl 151.
doc02	N/A (amendment instrument).	Repeal justified on reducing regulatory burden/cost; limited amendments to 1981 <i>Act</i> .	Does not reinstate pre-market device approvals; limited changes under 1981 framework.	No explicit mention of Rongoā or Te Tiriti.	Incremental amendment post-repeal.	Frame: red tape/compliance costs; consumer choice/affordability.	Industry support from NHP and some device sectors.	Select committee and Cabinet materials emphasise burden/cost.
doc03	Legacy act; gaps for devices, SaMD, and contemporary products.	N/A.	No general pre-market authority for devices; fragmented oversight.	No recognition of Rongoā.	Baseline regime revived post-repeal.	Minimalist, post-market oversight.	-	<i>Act</i> text shows absence of device pre-market approval.
doc04	Acknowledges reform background but pivots to cost concerns.	Primary objective: remove unnecessary compliance costs and regulatory burden (NHP, devices).	Accepts loss of <i>TPA</i> powers as trade-off for deregulation.	Silent on Rongoā/Te Tiriti.	Rapid repeal pre-implementation.	Strong “red tape” framing.	Business/industry audience.	Quote: “remove unnecessary red tape...” (Cabinet Minute).
doc05	1981 <i>Act</i> not fit for purpose; risks to safety and access; need comprehensive framework.	N/A.	Justifies <i>TPA</i> 's stronger authorities incl. device approvals and SaMD.	Addresses Rongoā Māori and Te Tiriti obligations (see RIS Rongoā).	Supports comprehensive reform.	Modernisation/patient safety.	Clinical and public interest audience.	RIS language on fit-for-purpose and safety risks.
doc06	Supports <i>TPA</i> aims and structure.	N/A.	Endorses device oversight and modern powers.	Considers cultural provisions as appropriate.	Parliamentary scrutiny affirmed need.	Modernisation/safety framing.	Varied submitters; overall supportive of reform.	Report text.

Appendix Table 2 (continued): Framework matrix (full table).

doc_id	Problem definition	Repeal drivers	Lost protections	Rongoā_Tiriti	Reform dynamics	Framing contest	Stakeholder positions	Key quotes
doc07	Notes repeal context.	Repeal framed as burden reduction and cost relief.	Recognises that <i>TPA</i> powers will not persist.	No references to Rongoā/Te Tiriti.	Rapid legislative process.	Regulatory burden/cost framing.	Industry and consumer-choice arguments salient.	Final report text.
doc08	-	Varies; likely focussed on clinical safety.	Supports patient safety via device oversight (inference from clinical stance).	-	-	Safety framing.	Clinical college position.	See evidence_excerpts_R1_v20250925.md
doc09	-	-	-	-	-	-	-	See evidence_excerpts_R1_v20250925.md
doc10	-	-	-	-	-	-	-	See evidence_excerpts_R1_v20250925.md
doc11	Reform background.	-	-	-	-	-	-	See evidence_excerpts_R1_v20250925.md
doc12	-	-	-	-	-	-	-	See evidence_excerpts_R1_v20250925.md
doc13	-	-	-	-	-	-	-	See evidence_excerpts_R1_v20250925.md
doc14	-	Summarises repeal justifications (burden/cost).	Notes absence of <i>TPA</i> powers post-repeal.	No substantive Rongoā content.	-	Burden/cost.	-	Report text.

Appendix Table 2 (continued): Framework matrix (full table).

doc_id	Problem definition	Repeal drivers	Lost protections	Rongoā_Tiriti	Reform dynamics	Framing contest	Stakeholder positions	Key quotes
doc15	Overview of modernising medicines regulation; context for TPA/MAB.	-	-	-	-	-	-	See evidence_excerpts_R1_v20250925.md
doc16	NHP regulation options; risk-based approaches.	Concerns about over-regulation raised.	-	-	-	Regulatory burden theme present.	NHP sector.	See evidence_excerpts_R1_v20250925.md
doc17	-	Cabinet material on repeal; reiterates burden reduction aims.	Accepts rollback of TPA authorities.	Silent on Rongoā.	-	“Red tape” frame.	Business focus.	See evidence_excerpts_R1_v20250925.md
doc18	Pharmacy ownership/licensing RIS provides context for system gaps.	-	-	-	-	-	-	See evidence_excerpts_R1_v20250925.md
doc19	Explicitly acknowledges need for culturally appropriate framework re Rongoā.	-	Supports Rongoā safeguards within TPA.	Links to Te Tiriti obligations; proposes Advisory Committee.	-	-	-	Quote: “provide a framework that acknowledges ... Rongoā Māori ... consistent with the Crown’s obligations under Te Tiriti ...”
doc20	-	-	-	-	-	-	-	Act shows notification/adverse event model, not pre-market approvals.

Appendix Table 2 (continued): Framework matrix (full table).

doc_id	Problem definition	Repeal drivers	Lost protections	Rongoā_Tiriti	Reform dynamics	Framing contest	Stakeholder positions	Key quotes
doc21	-	-	-	-	-	-	-	Dietary supplements regime - minimal efficacy/quality requirements.
doc22	-	-	Warns of risks without device pre-market approval; patient safety concerns.	-	-	Safety framing.	Clinical stakeholder.	Paraphrase: removal of pre-market approval exposes patients to device risks.
doc23	-	Supports repeal to reduce burden; consumer choice.	-	-	-	Burden/choice.	NHP industry.	See evidence_excerpts_R1_v20250925.md
doc24	-	Supports repeal due to compliance costs; export considerations.	-	-	-	Burden/cost.	Dairy exporter.	See evidence_excerpts_R1_v20250925.md
doc25	-	Coalition agreements emphasise removing red tape for NHP and streamlining device regulation.	-	Silent on Rongoā in agreements.	Signals deregulatory priorities.	“Red tape” framing.	Political parties.	Beehive coalition agreements page.

Appendix Table 3: Sample results table (to fill).

Theme	% Agreement	κ	Notes
Problem definition			
Repeal drivers			
Lost protections			
Rongoā /Te Tiriti			
Reform dynamics			
Framing contest			
Stakeholder positions			

Appendix Table 4: Intra rater reliability results.

Theme	% Agreement	κ	Notes
Problem definition	0.83	0.67	One discrepancy (doc07 coded as context in recode)
Repeal drivers	1.00	1.00	Full agreement
Lost protections	1.00	1.00	Full agreement
Rongoā /Te Tiriti	1.00	1.00	Full agreement
Reform dynamics	1.00	1.00	Full agreement
Framing contest	1.00	1.00	Full agreement
Stakeholder positions	1.00	1.00	Full agreement

Mean κ across themes: 0.95 (range 0.67–1.00).

Appendix Table 5: Reliability results.

Theme	Percent agreement	Cohens kappa
Framing contest	1.00	1.00
Lost protections	1.00	1.00
Problem definition	0.83	0.67
Reform dynamics	1.00	1.00
Repeal drivers	1.00	1.00
Rongoā/Te Tiriti	1.00	1.00
Stakeholder positions	1.00	1.00

Appendix Figure 1: Selection flow.

