

# Reform, repeal, replace: a case study of policy whiplash in New Zealand's health sector

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## ABSTRACT

**AIMS:** For over a decade, New Zealand pursued a comprehensive reform of its outdated medicines legislation, culminating in the passage of the *Therapeutic Products Act 2023 (TPA)* in 2023. In a policy reversal, the *Act* was repealed by a new government in 2024. This study provides an analysis of this policy cycle to understand the drivers of the reform, its subsequent repeal and the implications for future health policy. We take a political economy perspective, foregrounding health policy instability and its consequences for patients, clinicians and Māori health interests.

**METHODS:** We conducted a qualitative documentary policy analysis of 25 key government and stakeholder documents, including legislation, regulations, cabinet papers and select committee reports with their submissions. We employed a framework method for a systematic thematic analysis of the corpus to map and interpret the policy narratives.

**RESULTS:** The impetus for the *TPA* was a consensus that the *Medicines Act 1981* and its associated regulations from 1984 and 1985 were “no longer fit for purpose”. The repeal was driven by an ideological shift, reframing the *TPA* as an unacceptable “regulatory burden”. This has tangible consequences, including the loss of a pre-market approval framework for medical devices and the erasure of legislative provisions designed to protect and recognise Rongoā Māori (traditional Māori healing).

**CONCLUSION:** The *TPA* policy cycle is a case study in the fragility of evidence-based health reform. It demonstrates that without a durable, cross-party political consensus, long-term policy projects are highly vulnerable to being dismantled by short-term shifts in political ideology, with downstream harms from regulatory instability. It also illustrates how a targeted “micro-reform” can generate outsized system-level consequences.

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The regulation of therapeutic products is a core function of the modern state, representing a critical balance between fostering innovation, ensuring timely public access to beneficial products and protecting citizens from harm.<sup>1</sup> Globally, regulatory systems are in a constant state of evolution, adapting to new technologies such as biologics, software as a medical device, and cell-based therapies.<sup>2</sup> In this context, New Zealand's legislative framework had, for many years, been an outlier.<sup>3</sup> The *Medicines Act 1981* and its key supporting regulations—the *Medicines Regulations 1984*<sup>4</sup> and the *Dietary Supplements Regulations 1985*<sup>5</sup>—were widely acknowledged by policymakers and health professionals as being out of date.<sup>6</sup>

Recognising this deficit, successive New Zealand governments from 2011 onwards embarked on a long and detailed policy process to create a new comprehensive regulatory scheme.<sup>7</sup> This decade-long effort, involving extensive consultation with the industry, clinical bodies and the public, culminated in the passage of the *Therapeutic Products*

*Act (TPA)* in July 2023.<sup>8</sup> The *TPA* was a key piece of legislation, designed to create a single, modern and flexible scheme for all therapeutic products, finally bringing New Zealand into line with its international counterparts like Australia's Therapeutic Goods Administration (TGA).

However, the *TPA* was repealed in its entirety by a newly elected government in early 2024, before it had been fully implemented.<sup>9</sup> The repeal was followed by the introduction of the *Medicines Amendment Bill (MAB)*, a more limited piece of legislation that sought to amend the original 1981 *Act* rather than replace it.<sup>10</sup> This rapid cycle of reform, passage, repeal and replacement offers a case study in the dynamics of health policy and the challenges of achieving durable legislative change.<sup>11</sup>

**Brief political context:** The 2023 general election produced a coalition government whose coalition agreement and early ministerial statements emphasised reducing “regulatory burden” and “red tape” for therapeutic products, particularly natural health products and medical devices.<sup>12</sup>

We note these political signals as context for the repeal, but a comprehensive analysis of party manifestos and the coalition text is outside scope and is acknowledged as a limitation.

This study is a documentary policy analysis of this policy cycle through the lens of political economy. It seeks to move beyond the political headlines to systematically analyse the documentary record. In doing so, we can gain insight into the competing narratives and forces that shape policy decisions. Our analysis is guided by theories of the policy process, particularly John Kingdon's Multiple Streams Framework, which helps to explain how policy windows open and close,<sup>13</sup> and the Advocacy Coalition Framework, which illuminates how groups with shared beliefs compete to translate those beliefs into policy.<sup>14</sup>

This paper addresses the following research questions:

1. What key policy problems led to the creation of the *TPA*?
2. What were the primary drivers and justifications 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, 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?

New Zealand's reversal from a comprehensive, risk-proportionate regime to an incremental amendment provides an unusual natural experiment in how policy frames can rapidly displace one another within a single reform cycle. Yet systematic, document-based analyses of this pivot are scarce. We address this gap by assembling a defined corpus across legislative, cabinet and stakeholder sources and applying a transparent framework analysis to compare problem definitions, frames and concrete protections gained and lost across regimes. Figure 2 summarises our theory of change from inputs to outcomes, and Figure 3 shows the end-to-end workflow we followed.

## Methods

This study employed a qualitative documentary policy analysis, guided by the reporting standards

of the Standards for Reporting Qualitative Research (SRQR) checklist.<sup>15</sup> This approach was chosen to allow for a deep, contextualised understanding of the policy process as it unfolded through the official documentary record.<sup>16</sup>

## Data

The data corpus consisted of 25 publicly available documents, including the core legislation and regulations (*Medicines Act 1981*, *Medicines Regulations 1984*, *Dietary Supplements Regulations 1985*, *TPA*, *MAB*), associated cabinet papers and minutes, regulatory impact statements (RIS) and select committee reports. Because there were 16,756 submissions to the *TPA* repeal process,<sup>17</sup> a focussed approach was taken. We used purposeful sampling of organisational submissions (e.g., peak industry bodies, clinical/professional colleges) to represent key stakeholder groups rather than attempt an exhaustive review. Selection aimed to maximise coverage across sectors while avoiding duplication of substantively identical positions; sampling decisions were prespecified in the protocol and are documented in the Appendix. These documents were sourced from the official New Zealand Parliament and Ministry of Health – Manatū Hauora websites. Table 1 lists the corpus and document IDs used across the analysis.

## Analysis

We analysed the data using a framework method: a systematic and flexible approach to qualitative data analysis that is well suited to policy research.<sup>15</sup> The process involved five distinct stages:

1. **Familiarisation:** We read and re-read the documents to gain a comprehensive overview of the policy timeline, key actors and core arguments.
2. **Identifying a thematic framework:** We developed a coding framework of seven core themes. The initial framework was deductive, based on our five research questions. However, during the familiarisation stage, we allowed for inductive themes to emerge from the data. For example, the theme of "framing contest" was not pre-specified but became apparent as we analysed the documents.
3. **Indexing:** We systematically applied the thematic framework to the entire data corpus.
4. **Charting:** We summarised the data from the

documents into a framework matrix, with columns for each theme and rows for each document. This allowed for a systematic comparison of themes across the different documents and stakeholder groups.

5. **Mapping and interpretation:** We used the charted data to identify patterns, contradictions and dominant narratives across the documents.

We used the framework method with an *a priori* theme set derived from the research questions, refined during familiarisation and extended inductively to capture emergent concepts. One coder developed the initial codebook, then re-reviewed it after a 2-week wash-out to enhance consistency (intra-coder reliability step). The final framework comprised seven themes spanning problem definition, repeal drivers, lost protections, Rongoā Māori, reform dynamics, framing contest and stakeholder positions. This process was guided by our protocol; the protocol, reporting checklist, coding framework and the populated framework matrix are provided in the Appendix. For audit and reproducibility, we also supply a corpus registry with canonical links, a full framework matrix (25 documents×7 themes) and an excerpts compendium (doc-ID-linked quotes) in the Appendix.

**Reliability check:** To assess consistency of coding in this single-author study, we conducted an intra-rater reliability exercise on a stratified sample of six of 25 documents after a 14-day wash-out. Using binary presence/absence per theme, mean Cohen's  $\kappa$  was 0.95 (range 0.67–1.00). Full details and per-theme results are provided in the Appendix.

## Results

Our analysis of the documentary record reveals a narrative of a reform being disrupted by an ideological shift, with consequences for health regulation and Indigenous health rights.

Three patterns were salient across the corpus. First, provisions recognising Rongoā Māori present in the *TPA*—such as establishment of a Rongoā advisory committee and safeguards to avoid inadvertent capture—are absent from repeal and amendment materials (Table 2). Second, the dominant frame shifts from “modernisation for public safety and international alignment” to “regulatory burden and cost”, with justification audiences moving from clinicians/patients to

businesses/consumers (Table 3). Third, several concrete protections embedded in the *TPA*—most notably pre-market medical device oversight and enhanced information-gathering powers—do not persist under the *Medicines Act* framework post-repeal (Table 4).

### The uncontested case for reform

The documents leading to the passage of the *TPA* reveal a consensus on the core problem: the *Medicines Act 1981* and its supporting regulations were obsolete. A 2022 regulatory impact statement from the Ministry of Health – Manatū Hauora was unequivocal, stating that the old *Act* “is not fit for purpose for a modern, globalised healthcare environment” and that its limitations “create risks for patient safety and prevent timely access to needed products.”<sup>18</sup> This was not a contested view; it was the foundational assumption of the entire reform project. The documents detail specific, critical gaps the *TPA* was designed to close, including the lack of a pre-market approval system for medical devices under the *Medicines Regulations 1984*,<sup>4</sup> the inability to regulate software as a medical device and the minimal oversight for natural health products under the *Dietary Supplements Regulations 1985*.<sup>5</sup>

### The repeal: a new narrative of “regulatory burden”

The documents justifying the repeal of the *TPA* do not challenge the original problem diagnosis. Instead, they introduce a new, competing narrative that reframes the issue. The language shifts dramatically from a focus on safety and modernisation to a focus on economic efficiency and compliance costs, providing clear evidence of a framing contest (see Table 3). A key 2024 cabinet minute justifying the repeal states the government's primary objective is to “remove the unnecessary compliance costs the *TPA* would have imposed on the natural health products and medical device sectors.”<sup>12</sup> This narrative of “regulatory burden” and “red tape” is the central justification for the repeal; a position supported by a wide range of industry stakeholders, from large dairy exporters to small health food companies, in the context of 16,756 submissions to the Health Select Committee on the *Therapeutic Products Act Repeal Bill*.<sup>17,19</sup>

### Select consequences of the policy reversal

#### 1. The loss of key regulatory protections

A consequence of the repeal was the loss of a modern, comprehensive regulatory framework for medical devices and other products. The *TPA* would have closed major gaps in the 1981 *Act* and its 1984 regulations. As detailed in Table 4, these lost protections include the power for pre-market approval of all medical devices, a clear framework for regulating software as a medical device and consistent oversight for clinical trials. The impact of this was a key point of contention for clinical stakeholders. One clinical submission on the repeal *Bill* expressed concern that removing pre-market approval would return New Zealand to a regulatory deficit and expose patients to unacceptable device risks.<sup>20</sup> The *MAB*, which replaced the *TPA*, did not reinstate these provisions, instead making more limited amendments to the 1981 *Act*.<sup>21</sup>

## 2. The erasure of Rongoā Māori protections

A second consequence of the repeal is the erasure of specific legislative protections for Rongoā Māori. The *TPA* was a landmark in this regard. Part 7, Clause 151 of the *Act* mandated the creation of a “Rongoā Advisory Committee” to ensure Māori perspectives were integrated into the regulatory process.<sup>8</sup> An accompanying RIS document justified this by stating a key objective was “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*.”<sup>22</sup>

In contrast, the documents justifying the repeal are silent on this matter. The cabinet papers and the *MAB* itself contain no mention of Rongoā, *Te Tiriti* or the impact of the repeal on Māori health interests.<sup>12</sup> This absence effectively nullifies the legislative recognition and protection that had been achieved, representing a policy reversal on Indigenous health rights; albeit, the *Bill* also has the effect of being less restrictive of natural therapeutic products, including those used in Rongoā (see Table 2).<sup>23</sup> While some submitters to the select committee on the repeal *Bill* raised this issue, the final report recommended the *Bill* be passed without amendment.

## Discussion

The rise and fall of the *TPA* is a case study in the fragility of health policy reform. Our analysis, viewed through the lens of policy theory, suggests that while the policy may have been well founded on technical and safety grounds,

its fate was ultimately determined by political forces, illustrating key concepts from policy theory.<sup>24</sup> The decade-long development of the *TPA* can be seen as a “policy window”<sup>13</sup> opening, where a recognised problem (outdated act) and a developed solution (the *TPA*) aligned. However, the change in government created a new political stream that abruptly closed this window.<sup>13</sup>

**Contribution and novelty:** This analysis formalises, in a transparent and auditable way, what many practitioners perceived informally—namely that targeted, seemingly “small” legislative changes can create outsized system-level effects. By situating the *MAB* as a micro-reform with macro consequences, we add to international literature and to the under-developed political economy of health in New Zealand and Australia. As in clinical epidemiology, codifying “the obvious” via systematic documentation provides a citable evidence base that can influence practice and policy.

Taken together, our findings indicate that the repeal reflected a successful reframing campaign rather than new evidence overturning the case for modernisation. In small markets, where regulatory capacity and political attention are thin, durable reform likely requires *ex ante* consensus devices (e.g., cross-party commitments on core safety provisions), phased commencement to de-risk early implementation and statutory review points tied to public reporting. Absent these design features, comprehensive frameworks may be vulnerable to rapid policy reversal when electoral incentives favour short-horizon deregulatory narratives.

The repeal was facilitated by the success of a new “advocacy coalition”,<sup>14</sup> composed of the new governing parties and industry groups (particularly from the natural health products [NHP] sector), which prioritised economic deregulation. This coalition successfully reframed the *TPA* from a necessary safety modernisation to an instance of excessive “regulatory burden”. This framing contest is central to understanding the outcome. The “patient safety” narrative, while technically sound, was complex and long term. The “regulatory burden” narrative resonated with a broader political agenda of reducing the size of the state. This narrative is not new to therapeutic regulation and indeed Sam Peltzman’s work on drug regulation specifically describes the trade-off between access to therapeutic products and restrictive regulation—

consumer safety is impacted in both polarities of this trade-off.<sup>25</sup> This offers a lesson for public health advocates: the technical merits of a policy may be insufficient for its political survival without a supporting narrative that is equally simple and powerful.<sup>26,27</sup>

The consequences of this policy reversal are significant. The loss of a modern regulatory framework for medical devices leaves New Zealand as an outlier among developed nations and arguably compromises consumer safety.<sup>28</sup> The erasure of the Rongoā Māori provisions is arguably a significant setback for Māori health equity (in terms of recognition and representation) and the Crown's commitment to its Te Tiriti o Waitangi obligations.<sup>29,30</sup> It highlights the risk that when complex, comprehensive reforms are dismantled, specific, hard-won protections for minority or less powerful groups can be the first to be discarded as politically expendable.

This “policy whiplash” is not a new phenomenon in New Zealand. The country has a history of ideologically driven health reforms across the political spectrum, followed by periods of reversal or course correction.<sup>3,31</sup> The market-oriented reforms of the 1990s, for example, were substantially unwound in the 2000s. The *TPA* policy cycle, however, is an example of this trend, given the decade-long development process and the broad consensus that underpinned the original reform. The *Pae Ora (Health Futures) Act 2022* reforms themselves have arguably flipped from a devolved model into a full centralised model, with signs of progressive devolution from regional to district level, in less than 3 years.<sup>32</sup> This suggests that the New Zealand health policy landscape may be becoming more polarised and that the potential for long-term, evidence-based policy is being undermined by short-term political cycles (again, across the political spectrum).

The repeal of the *TPA* can be seen as a case of “punctuated equilibrium” in policymaking, where long periods of incremental change are interrupted by rapid, transformative shifts. In this case, the “punctuation” was the 2023 election, which brought to power a government with a different set of policy priorities. The new government was able to challenge the dominant policy narrative and to replace it with a new one that was more in line with its own ideological commitments. This highlights the importance of understanding the political context in which policy is made. The *TPA* was not repealed because the evidence base for it was weak, but because the political environment

had changed.

This has important implications for the future of evidence-based policymaking in New Zealand. If long-term evidence-based policies can be so easily overturned by short-term political shifts, then there is a risk that policymakers will become more reluctant to invest in them. This could lead to a more reactive and less strategic approach to policymaking, with a greater focus on short-term political gains than on long-term public good. To avoid this, it is essential that there is a broad-based political and public consensus on the importance of evidence-based policymaking. This will require a commitment from all political parties to engage in a more constructive and evidence-based debate about the future of the country.

This study has limitations. We prioritised timeliness to document an active policy reversal; accordingly, we traded some completeness for speed, focussing on a defined, auditable corpus. Coding was undertaken by a single analyst and is restricted to publicly available documents; unpublished advice and private lobbying may not be fully captured. New Zealand's *Official Information Act 1982* regime and common redactions limit access to internal documents, and some materials may never be released. We did not triangulate with key-informant interviews. Strengths include a pre-specified framework, a defined corpus spanning legislation, cabinet and stakeholder submissions (Table 1), and full transparency of the codebook and framework matrix in the Appendix. As a documentary analysis, it cannot capture private deliberations, lobbying efforts or informal negotiations that undoubtedly influenced the outcome. While we sought to analyse a wide range of submissions, the official documentary record does not fully capture the views of all stakeholders, particularly individual patients or smaller community groups; the author's positionality as a medical professional and health economist may have influenced interpretation. We also did not undertake a comprehensive analysis of party manifestos, coalition agreements or Hansard beyond targeted references; this broader political analysis is acknowledged as outside scope. To avoid tokenism, Te Ao Māori aspects are treated briefly here and are the focus of a dedicated follow-up analysis on Rongoā Māori and Article 2 of Te Tiriti.<sup>33</sup> Future research employing interviews with key policymakers and stakeholders would add explanatory depth. To support trustworthiness in this single-author study, we also performed an intra-rater reliability check on a stratified sample

of six of 25 documents after a 14-day wash-out; mean Cohen's  $\kappa$  was 0.95 (range 0.67–1.00), with full details provided in the Appendix.

## Conclusion

The repeal of the *Therapeutic Products Act 2023* was a key moment in New Zealand's health policy history. It was not a simple administrative change but an ideologically driven policy reversal with significant consequences. It resulted in the specific loss of a modern regulatory framework for medical devices and the removal of legislative recognition for Rongoā Māori. More broadly, this case study provides an illustration of the challenges of achieving long-term, evidence-based policy change. It demonstrates that for major health reforms to be durable, they must not only be technically sound and supported by evidence, but they must also command a resilient political and public consensus capable of withstanding the inevitable shifts in government and ideology.

## Ethics

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.

## Funding

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

## Data availability

All source materials are publicly available; the complete corpus list, protocol, codebook and the populated framework matrix are provided in the Appendix.

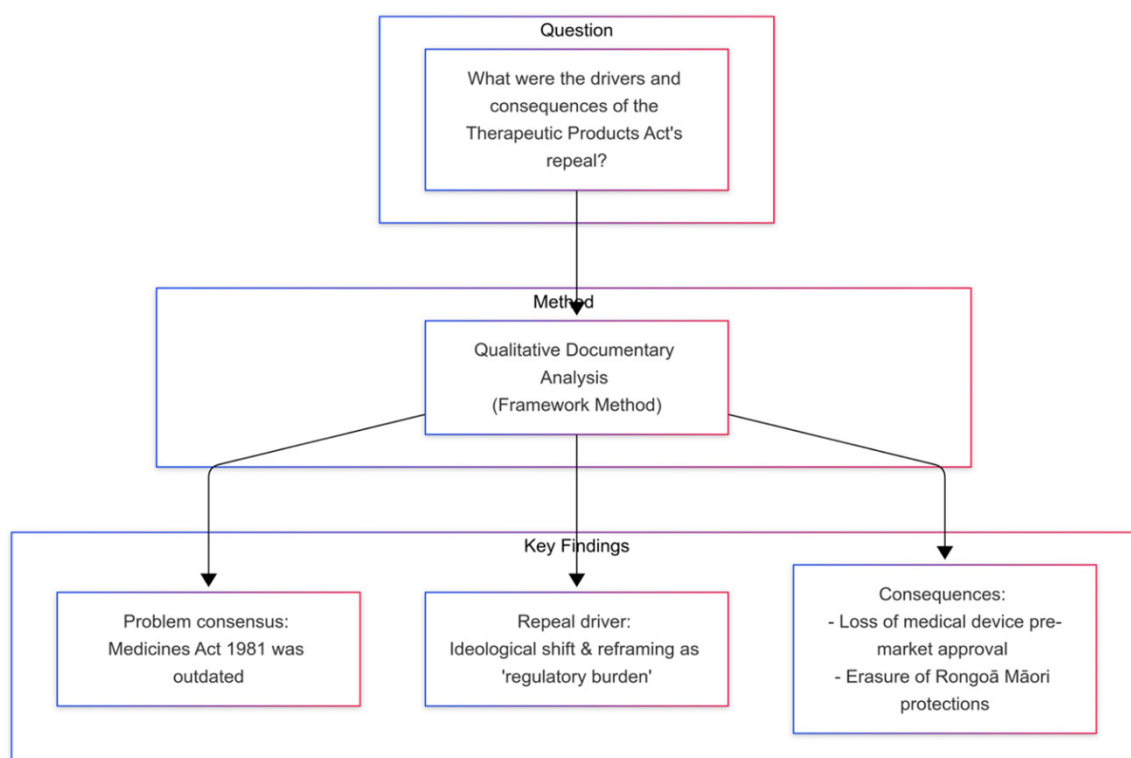
## Figures

Figure 1 provides a compact visual summary of the study's core question, method and key findings.

Figure 2 illustrates the conceptual flow of the study, linking the inputs (source materials and theoretical frameworks) to the research activities, outputs and ultimate outcomes.

Figure 3 shows the end-to-end workflow for the study, from the initial collection of data sources through to the final submission of the manuscript.

**Figure 1:** Graphical abstract.



## Tables

Table 1 details the 25 primary source documents that constitute the corpus for the qualitative documentary policy analysis. The documents were collected from publicly available New Zealand government, parliamentary and stakeholder sources. They cover the legislative and policy cycle of the *Therapeutic Products Act 2023*, from its development to its subsequent repeal and replacement by the *Medicines Amendment Bill*. Each document is assigned a unique ID used for reference within the analysis.

Table 2 compares the treatment of Rongoā

Māori (traditional Māori healing) in documents related to the *Therapeutic Products Act (TPA)* versus those related to the *Medicines Amendment Bill (MAB)* and the *TPA's* repeal.

Table 3 provides evidence for the shift in policy framing by comparing the language used in documents from the *TPA* era (focussed on safety and modernisation) with the *Repeal* era (focussed on regulatory burden and cost).

Table 4 details specific regulatory powers and consumer protections that were included in the *Therapeutic Products Act 2023* but are absent from the *Medicines Act 1981* framework that remains in place following the repeal.

Figure 2: Conceptual model.

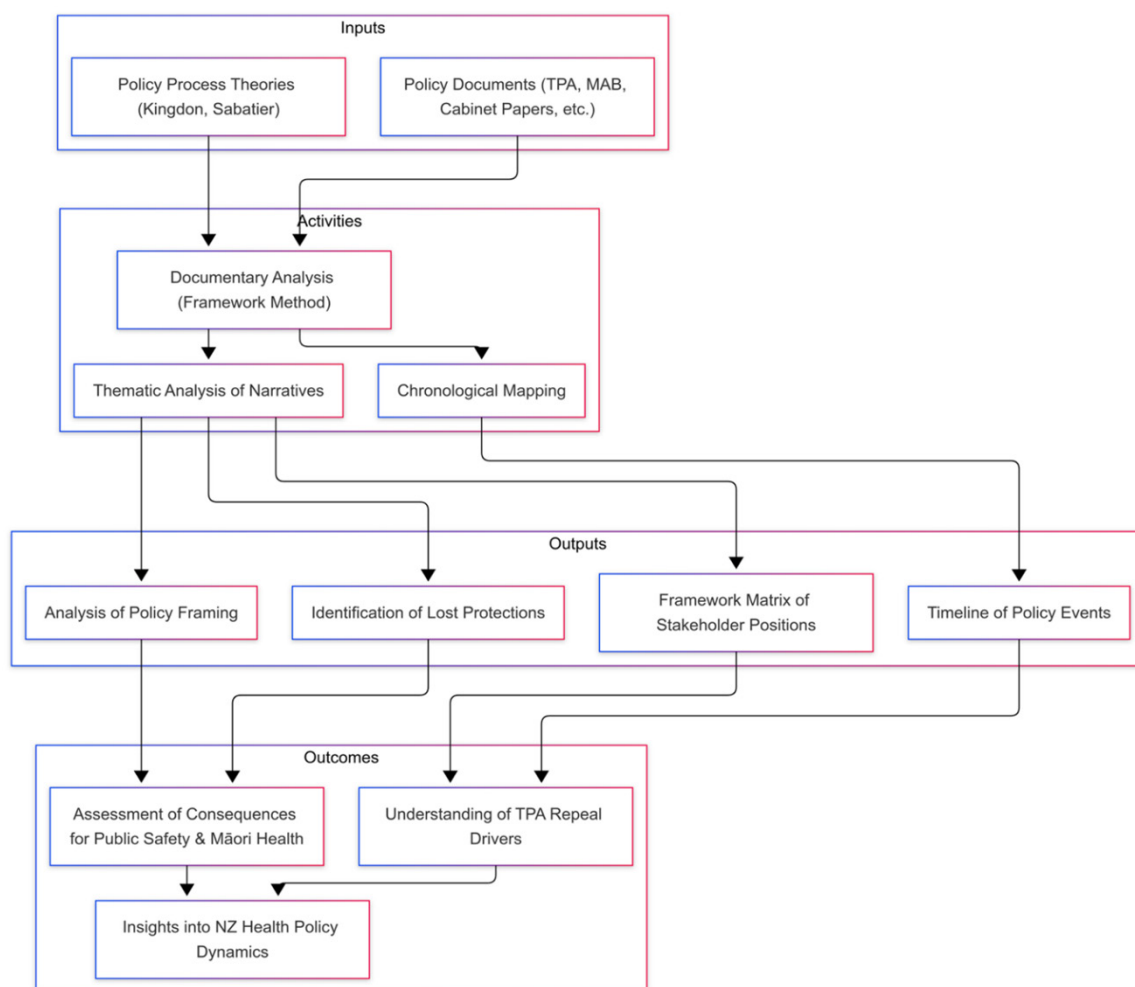


Figure 3: Methods workflow.

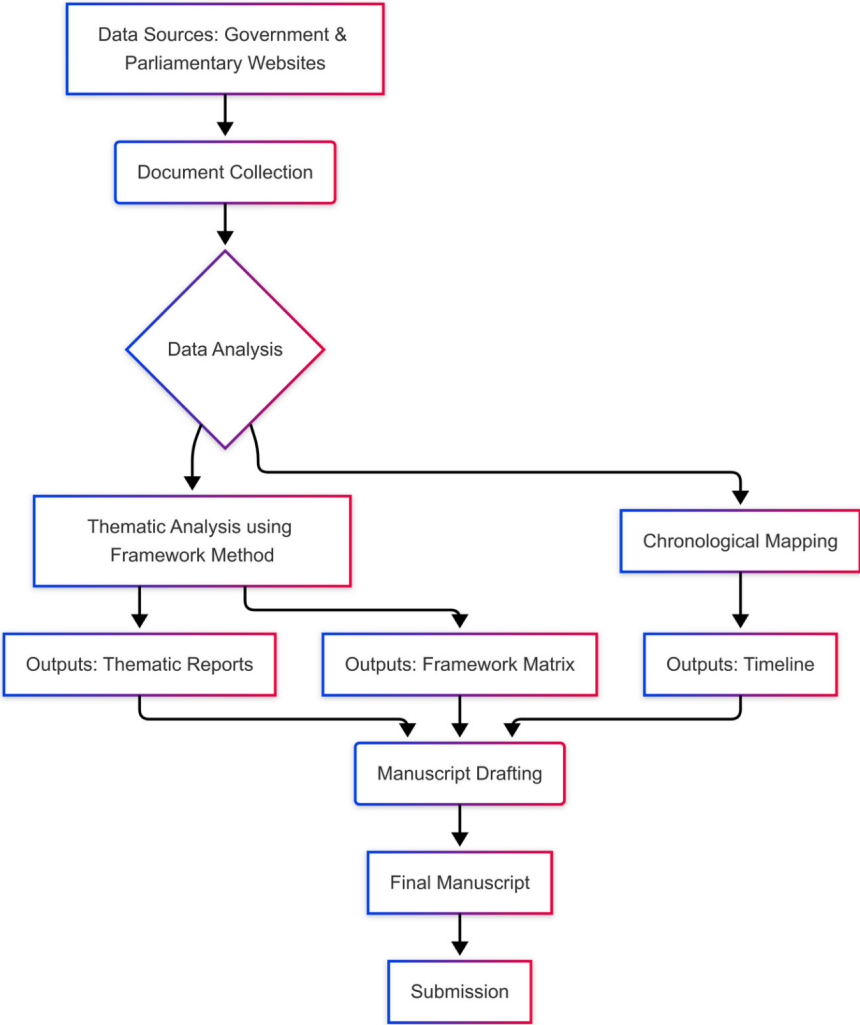


Table 1: Corpus of documents analysed.

Document ID	Title	Source	Year	Citation
doc01	Therapeutic Products Act 2023	New Zealand Parliament	2023	8
doc02	Medicines Amendment Bill	New Zealand Parliament	2024	10
doc03	Medicines Act 1981	New Zealand Parliament	1981	34
doc04	Cabinet Paper: Repealing the Therapeutic Products Act	Ministry of Health – Manatū Hauora	2024	12
doc05	Regulatory Impact Statement: Therapeutic Products Bill	Ministry of Health – Manatū Hauora	2022	18
doc06	Select Committee Report: Therapeutic Products Bill	New Zealand Parliament	2023	35

**Table 1 (continued):** Corpus of documents analysed.

Document ID	Title	Source	Year	Citation
doc07	Select Committee Report: TPA Repeal Bill	New Zealand Parliament	2024	17
doc08	Submission: ANZCA on TPA Repeal	Stakeholder	2024	36
doc09	Submission: CNA on TPA Repeal	Stakeholder	2024	37
doc10	Submission: CMC on TPA Repeal	Stakeholder	2024	38
doc11	Briefing and Cabinet material	Ministry of Health – Manatū Hauora	2022	39
doc12	cab-22-min-0536	Ministry of Health – Manatū Hauora	2022	40
doc13	crown-liability-under-the-therapeutic-products-bill...	Ministry of Health – Manatū Hauora	2022	41
doc14	Final report (Therapeutic Products Act Repeal Bill)	New Zealand Parliament	2024	42
doc15	Modernising the Regulation of Medicines...	Ministry of Health – Manatū Hauora	2024	43
doc16	regulating-natural-health-products-cab-paper-redacted	Ministry of Health – Manatū Hauora	2022	44
doc17	Repealing the Therapeutic Products Act...	Ministry of Health – Manatū Hauora	2024	45
doc18	RIS Pharmacy Ownership and Licensing	Ministry of Health – Manatū Hauora	2022	46
doc19	RIS TPB Rongoā and Small-Scale Producers	Ministry of Health – Manatū Hauora	2022	22
doc20	Medicines Regulations 1984	New Zealand Parliament	1984	4
doc21	Dietary Supplements Regulations 1985	New Zealand Parliament	1985	5
doc22	Submission: NZ Dental Association on TPA Repeal	Stakeholder	2024	20
doc23	Submission: NZ Health Food Company on TPA Repeal	Stakeholder	2024	47
doc24	Submission: Fonterra on TPA Repeal	Stakeholder	2024	48
doc25	Coalition Agreement 2023	New Zealand Government	2023	49

**Table 2:** Comparison of Rongoā Māori provisions.

Document set	Provisions and mentions of Rongoā Māori
<b>Therapeutic Products Act (TPA) &amp; associated documents</b>	<ul style="list-style-type: none"> <li>- The <i>TPA</i> itself contained a specific clause (Part 7) creating a Rongoā Advisory Committee to provide advice to the regulator.</li> <li>- The <i>Act</i> included provisions to ensure Rongoā products were not inadvertently captured by the definition of a “therapeutic product”.</li> <li>- The regulatory impact statement explicitly analyses the impact of the legislation on Rongoā practitioners and discusses the Crown’s obligations under Te Tiriti o Waitangi.</li> <li>- Cabinet papers leading to the <i>TPA</i> discuss the need for a culturally appropriate framework that respects and protects the practice of Rongoā.</li> </ul>
<b>TPA Repeal Bill &amp; Medicines Amendment Bill (MAB) documents</b>	<ul style="list-style-type: none"> <li>- The <i>TPA Repeal Bill</i> contains no mention of Rongoā Māori or the disposition of the <i>TPA</i>’s Rongoā provisions.</li> <li>- The <i>Medicines Amendment Bill</i> is silent on the issue of Rongoā Māori.</li> <li>- The cabinet papers and minutes justifying the repeal of the <i>TPA</i> and the introduction of the <i>MAB</i> make no mention of Rongoā, Te Tiriti or the impact of the repeal on Māori health interests. The focus is exclusively on economic impacts and reducing regulatory burden.</li> </ul>

**Table 3:** Comparative analysis of policy framing.

Policy theme	TPA-era documents (2022–2023)	Repeal-era documents (2024)
<b>Primary problem definition</b>	“The current Medicines Act 1981 is no longer fit for purpose and does not adequately protect the public from the risks associated with modern therapeutics.” (Ministry of Health – Manatū Hauora RIS, 2022)	“The Therapeutic Products Act 2023, in its current form, would impose an unacceptable level of regulatory burden on industry...” (Cabinet Minute, 2024)
<b>Goal of legislation</b>	“To provide for the comprehensive and risk-proportionate regulation of therapeutic products in a way that protects public health and safety, while supporting access to necessary and innovative products.” ( <i>TPA</i> , Part 1, Clause 3)	“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 <i>TPA</i> ’s proposed scheme.” (Cabinet Minute, 2024)
<b>View of regulation</b>	Regulation is presented as a necessary tool for public protection and a facilitator of international alignment and innovation.	Regulation is presented as a primary barrier to business, innovation, and consumer choice, particularly for the NHP sector.

**Table 3 (continued):** Comparative analysis of policy framing.

Policy theme	TPA-era documents (2022–2023)	Repeal-era documents (2024)
<b>Key language</b>	“Modernisation”, “Patient Safety”, “Fit for Purpose”, “International Best Practice”, “Comprehensive Framework”	“Regulatory Burden”, “Compliance Costs”, “Red Tape”, “Unnecessary”, “Costly”
<b>Target audience of justification</b>	The justification is aimed at the public and health professionals, emphasising safety and improved health outcomes.	The justification is aimed at business owners and consumers, emphasising lower costs and freedom of choice.

**Table 4:** Analysis of lost regulatory protections (*TPA vs Medicines Act 1981*).

Feature/regulatory power	Provision in <i>Therapeutic Products Act 2023 (TPA)</i>	Status under <i>Medicines Act 1981 (post-Repeal)</i>	Implication of loss
<b>Medical device regulation</b>	Required pre-market approval for all medical devices based on their risk classification. (Part 5, Clause 82)	No general pre-market approval authority for medical devices. Regulation is largely post-market, relying on notifications and adverse event reporting.	Higher risk of unsafe or ineffective medical devices reaching the public. New Zealand remains an outlier among developed countries.
<b>Software as a medical device (SaMD)</b>	Explicitly included SaMD within the definition of a “therapeutic product”, allowing for modern, risk-based regulation.	The 1981 Act has no clear or adequate mechanism for regulating software, creating significant ambiguity and regulatory gaps.	Lack of oversight for health apps and clinical software, which may pose risks to patients if they are inaccurate or faulty.
<b>Regulation of natural health products (NHPs)</b>	Created a risk-based pathway for NHPs, requiring evidence for health claims and manufacturing quality standards.	NHPs are primarily regulated as “dietary supplements”, with minimal requirements for proving efficacy or quality.	Consumers may be misled by unsubstantiated health claims, and there is less assurance of product quality and consistency.
<b>Clinical trial regulation</b>	Established a single, consistent framework for approving and overseeing all clinical trials for therapeutic products.	Clinical trials are regulated under a less comprehensive and more fragmented set of guidelines.	Potential for inconsistencies in ethical oversight and safety standards for clinical trials across different types of products.
<b>Regulator’s information-gathering powers</b>	Granted the regulator broad powers to require information from any person in the supply chain to assess the safety and quality of a product.	The regulator’s powers are more limited and less clearly defined, potentially slowing down safety investigations.	Slower response to emerging safety signals and greater difficulty in ensuring compliance across the supply chain.

**COMPETING INTERESTS**

The author has previously been an advisor to Pharmac, is a member of multiple medical professional organisations such as the Royal Australasian College of Physicians (RACP) and Royal Australasian College of Medical Administrators (RACMA). The author submitted to Parliament on the *Medicines Amendment Bill*, in relation to section 19 and use of unapproved medicines by paramedics.

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**URL**

<https://nzmj.org.nz/journal/vol-138-no-1627/reform-repeal-replace-a-case-study-of-policy-whiplash-in-new-zealand-s-health-sector>

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## 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
<b>Cabinet Minute: Repealing the TPA (2024)</b>	<b>2.0 Repeal drivers</b>	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  $\kappa$  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  $\kappa$  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
	<b>4.3 Regulatory burden</b>	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>
	<b>6.0 Te Tiriti o Waitangi</b>	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)
<b>RIS: Rongoā &amp; Small-Scale Producers (TPA era)</b>	<b>1.0 Policy drivers</b>	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>
	<b>6.0 Te Tiriti o Waitangi</b>	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>
<b>Submission: Clinical body (CMC on MAB)</b>	<b>5.0 Lost protections</b>	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>
	<b>2.0 Repeal drivers</b>	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>
<b>Therapeutic Products Act 2023 (The Act itself)</b>	<b>5.0 Lost protections</b>	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>
	<b>6.0 Te Tiriti o Waitangi</b>	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>
<b>Coalition agreement (2023)</b>	<b>2.0 Repeal drivers/4.0 Framing contest</b>	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 <i>TPA/MAB</i> .	-	-	-	-	-	-	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 <i>TPA</i> authorities.	Silent on Rongoā.	-	“Red tape” frame.	Business focus.	See evidence_excerpts_R1_v20250925.md
doc18	Pharmacy ownership/licensing <i>RIS</i> 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 <i>TPA</i> .	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	-	-	-	-	-	-	-	<i>Act</i> 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	$\kappa$	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	$\kappa$	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  $\kappa$  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.

