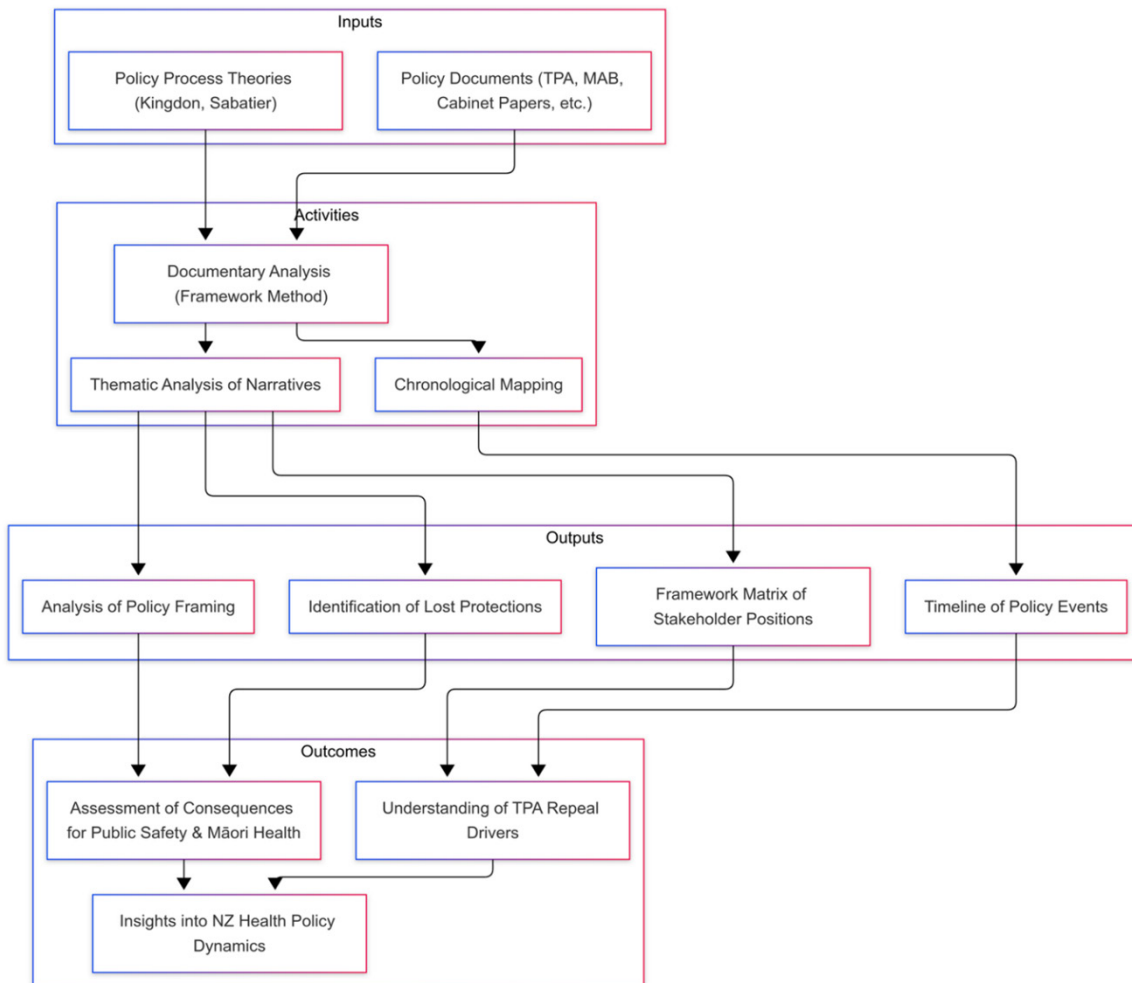


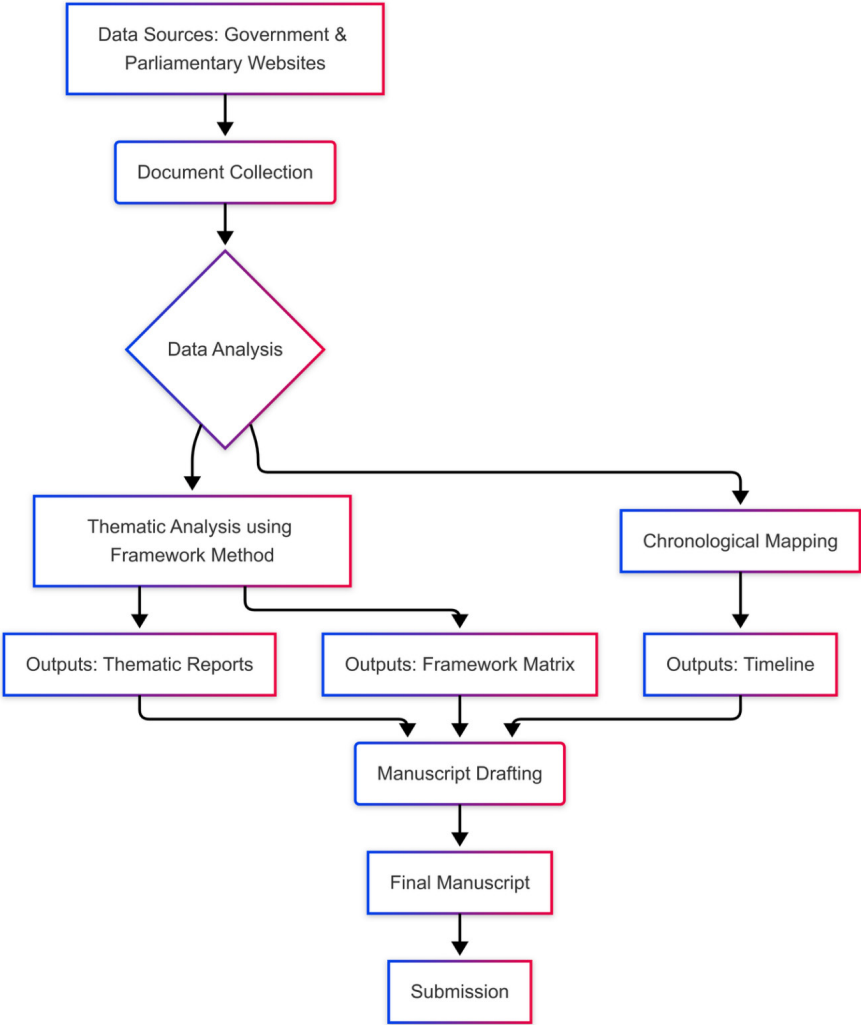
Figure 1: Graphical abstract.



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.