Open Public Letter

27th March 2026

To Prime Minister Luxon and Ministers,

Subject: Use of the Term “Effective” in the “Safe and Effective” Narrative – Logical, Evidential and Constitutional Concerns – Lessons Learned Phase 2 Report

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1. Introduction and Issue

We write to draw your attention to the use of the word “effective” within the “safe and effective” narrative as it relates to the Pfizer-BioNTech COVID-19 vaccine, marketed as Comirnaty (BNT162b2), and the implications this has for the validity of that description at the time it was conveyed to the New Zealand public.

The Lessons Learned Phase Two Report records that vaccine effectiveness was “waning” toward the end of 2021 and into 2022. However, this gives rise to a fundamental problem.

2. State of Knowledge at Rollout

At the time the rollout began in early 2021, effectiveness had not been established and remained to be determined through real-world use. Notwithstanding this, officials repeatedly described the vaccine to the public as “safe and effective,” ostensibly on the basis that its effectiveness had been established.

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3. Meaning and Requirements of “Effectiveness”

For the purposes of this letter, “effectiveness” is used in the ordinary sense conveyed to the public — namely, that the product would materially prevent infection and transmission at a population level.

Effectiveness, in its ordinary and accepted meaning, requires real-world demonstration — that is, evidence derived from deployment across a population sufficient to establish that the product achieves its intended purpose.

4. Absence of Evidential Foundation

In this case, that evidential foundation did not exist at the point of rollout. Instead, the product was deployed into the population before effectiveness had been established, and the outcomes of that deployment were relied upon to determine whether the product was, in fact, effective.

5. The Resulting Contradiction

This creates a clear contradiction. The product was described to the public as “effective” at a time when its effectiveness had not yet been established.

That contradiction is reinforced by the Commission’s statement that effectiveness was later “waning.” The concept of waning presupposes an established baseline. Without such a baseline, the proposition cannot be logically sustained.

6. Regulatory Position and Public Representation

The regulatory position further illustrates the issue. The Gazette notice imposed conditions to gather post-deployment data, meaning effectiveness was to be determined after rollout.

However, the public were told the product was already “safe and effective.”

A further and significant statutory consideration arises under section 20(3) of the Medicines Act 1983, which provides that:

“No consent given under this section shall be deemed to warrant the safety or efficacy of the medicine to which the consent relates.”

This provision makes clear that regulatory consent to the use of a medicine does not constitute a determination, assurance, or warranty that the product is either safe or effective.

Accordingly, at the point of rollout, not only had effectiveness not been established in an evidential sense, but the governing statutory framework expressly precluded any interpretation that regulatory approval itself amounted to confirmation of safety or efficacy.

In those circumstances, the repeated public description of the product as “safe and effective” cannot be reconciled with the statutory position under which the product was authorised.

7. The Disconnect and Evidential Conclusion

This creates a material disconnect between what was conveyed and what had been established.

It follows that the description of the product as “effective” was not supported by a sufficient evidential foundation at the time it was made.

8. Rollout Context and Real-World Outcomes

This issue must be considered in its full context.

The rollout of Comirnaty in New Zealand was advanced on the basis that the product was ostensibly “safe and effective.”

However, effectiveness had not been established in the real-world sense.

Subsequent widespread transmission and infection demonstrate that the product did not achieve effectiveness in the ordinary sense conveyed to the public.

9. Decision-Making and Misleading Effect

Where a medical product is presented as effective when effectiveness remains to be determined, that representation carries the capacity to influence decision-making.

The representation was relied upon by members of the public in making decisions of personal significance.

In circumstances involving lockdowns, mandates, and restrictions, that influence was heightened.

Accordingly, the representation was capable of misleading members of the public as to the true state of knowledge at the time.

10. Legal and Constitutional Implications

This observation does not proceed based on intent, but on the objective relationship between representation and knowledge.

In our submission, the circumstances described above engage fundamental protections recognised under both domestic and international law.

Section 8 and section 9 of the New Zealand Bill of Rights Act 1990 affirm the right to life and the right not to be subjected to treatment that is cruel, degrading, or disproportionately severe.

At the international level, Article 6 of the International Covenant on Civil and Political Rights recognises the inherent right to life.

Where public power is exercised on the basis of such representations, the existence of a sufficient evidential foundation is not optional but required.

A further matter arises from the fact that the determination of effectiveness was dependent upon data generated from population-wide use following rollout. In those circumstances, the public were, in effect, part of the process by which the product's effectiveness would be assessed.

Where individuals were subject to coercive measures — including mandates, restrictions, and conditions affecting participation in society — at a time when the product had not yet been fully understood in real-world terms, a legitimate question arises as to whether such circumstances are consistent with the protections afforded under section 10 of the New Zealand Bill of Rights Act 1990, which affirms the right not to be subjected to medical or scientific experimentation without consent.

This submission does not assert that section 10 has been breached, but rather that the relationship between post-deployment data generation, the conditions under which individuals were encouraged or required to participate, and the statutory protection afforded by section 10 warrants careful and independent legal examination.

From the perspective of the people, the Rule of Law requires that any exercise of public power be grounded in lawful authority and supported by a sufficient evidential foundation. Where that foundation is absent, and individuals are induced to act on the basis of representations that are capable of misleading, the legitimacy of that exercise of power is properly called into question.

Yours faithfully

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Schematic: Logical and Legal Structure of the "Effective" Representation

[1] INTRODUCTION
Claim: "Safe and Effective"
↓
Public understanding:
Protection from infection and transmission
↓

[2] STATE OF KNOWLEDGE
Effectiveness NOT established
Still being determined
↓

[3] MEANING OF EFFECTIVENESS
Requires:
→ Evidence
→ Real-world validation
→ Established baseline
↓

[4] ABSENCE OF FOUNDATION
No evidential basis at rollout
→ Population used to generate evidence
↓

[5] CONTRADICTION
Told: "effective"
Reality: not established
↓

[6] REGULATORY POSITION
Conditional approval
→ Post-deployment data required
→ Statute confirms no warranty of safety or efficacy
↓

[7] DISCONNECT
Representation ≠ evidence
→ Not supported by evidential foundation
↓

[8] REAL-WORLD OUTCOME
Widespread transmission

Widespread infection
→ Not effective in the ordinary sense conveyed
↓

[9] DECISION EFFECT
People relied on representation
Decisions made under pressure
→ Capable of misleading
↓

[10] LEGAL IMPLICATION
Raises questions of:
→ Lawful authority
→ Validity of consent
→ Protection of rights
→ NZBORA engaged (including s10)
→ ICCPR engaged
→ Population used in determining effectiveness under coercive conditions
→ Legitimacy of public power called into question