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MNZH MAKE NEW ZEALAND HEALTHY

Pause Drafting of the New Medical Products Bill. In Brief

THE PROBLEM: The Government is progressing a Medical Products Bill to replace the current Medicines Act. While it has been stated that "consultation will be included in the process of development of new legislation", there has been no recent publicly visible consultation on the substance of the Bill, nor any updated policy reassessment to support its development. The Bill is understood to be in drafting and expected to be introduced this year.

Government documents indicate that the framework will be 'risk proportionate', yet existing policy material shows that many foundational issues remain outside official consideration. With pre-policy consultation limited, any broader consultation will occur only once the draft Bill is released. By that stage, the underlying assumptions, core direction, and regulatory architecture will largely be settled. Consultation will therefore be constrained to technical amendments, with limited ability for lay or expert stakeholders to influence the fundamental design of the legislation.

Policy documents suggest an insufficient evidential and analytical foundation. Key scientific, clinical, and regulatory questions have not been examined during the policy formulation phase and are unlikely to be addressed in the draft legislation.

Current signals suggest that several issues central to contemporary medical practice and public health in New Zealand have not been adequately considered. Officials appear likely to rely on existing regulatory assumptions and international templates, often reflecting World Health Organization norms, without sufficient scrutiny of global best practice or whether these frameworks adequately address the realities of chronic illness, multimorbidity, and nutritional medicine in New Zealand.

he current pharmacovigilance system captures only a partial picture of harm. Non-serious but clinically significant adverse effects—including interaction-related harms, withdrawal phenomena, and impacts on quality of life—are not routinely visible in public datasets. Risks are not consistently stratified by age, sex, or vulnerability. Without statutory reform, safety monitoring will remain incomplete, limiting informed consent, clinical decision-making, and early detection of emerging risks.

Official materials also indicate limited evaluation of the evolving risk profile of biologic and advanced therapeutic products. These products, including monoclonal antibodies, gene therapies, and other biologics, raise distinct challenges, such as immunogenicity, manufacturing variability, contamination risk, and long-term safety uncertainty. They require robust, transparent post-market surveillance systems capable of detecting cumulative and subgroup-specific harms.

If these matters are not resolved at the outset, there is a significant risk that the legislation will entrench existing conceptual errors, including the overbroad 'therapeutic purpose' trigger, and extend medicines regulation into domains more appropriately governed by food and public health

frameworks. This would further enshrine the existing flaw in the statute, and carries with it long-term consequences for proportionality, access, informed consent and scientific coherence.

The continued use of a regulatory trigger based on 'therapeutic action' lacks a rational risk threshold and fails to reflect contemporary scientific understanding of human physiology. The scientific literature now shows that micronutrients function as integral components of cellular regulation and systemic resilience. Their safety is evaluated primarily through nutritional toxicology and exposure thresholds, such as upper intake levels, rather than pharmaceutical risk paradigms.

A modern regulatory framework must therefore apply greater precision and intensity to high-risk biologics, while avoiding unnecessary extension of medicines-level controls to low-risk nutritional or traditionally used substances. Without a scientifically grounded, risk-based classification system, regulatory burden risks being misallocated, diluting oversight where it is most needed and over-regulating where it is not.

For these reasons, proceeding with drafting in the absence of a coherent, evidence-based framework, risks producing legislation that is internally inconsistent, scientifically misaligned, and difficult to administer in practice. These omissions directly affect whether the future regulatory system will be capable of recognising real-world health outcomes at a population level.

THE SOLUTION: Cease drafting of the Medical Products Bill. Place a temporary moratorium on the legislative process, with the policy framework returned to a full consultation phase. This would enable the development of a proportionate, risk-based regulatory model that aligns legal definitions with biological reality and ensures that medicines law is directed to substances and products that genuinely warrant that level of control.

It is essential that a broad spectrum of foundational issues is clearly articulated before drafting proceeds. These matters determine the architecture of the regulatory system and directly affect the health and safety of New Zealanders. In particular, clarity is required on how substances are classified, how risk is defined, including drug–drug interaction risk, and where the legal boundary is drawn between food, nutrients, natural health products, and medicines. Key issues requiring resolution include:

- Declaration of officials and advisors, including relevant expertise, tasked with informing the underlying policy and legislation.
- Substantive, evidence-based review of biologic medicines and their distinct risk profiles.
- Clear statutory principles for regulatory decision-making.
- Evaluation of international best practice in medicines regulation and clinical trial design.
- Structural challenges in adverse-event reporting, including under-reporting and the exclusion of non-serious but clinically meaningful harms.
- Evaluation of polypharmacy and interaction risk, including harms arising from two-drug combinations.
- Streamlined access to Pharmac funding for nutrients with a long history of safe use.
- Development of an appropriate regulatory framework for natural health products.
- Consideration of risk-based classification models for nutrients.
- Assessment of disproportionate penalties applied to low-risk substances.