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Manatū Hauora | Ministry of Health

By email: therapeuticproducts@health.govt.nz

Tēnā koe

Natural Health Products Regulation

Te Whare Tohu o Te Hau Whakaora | The Australian and New Zealand College of Anaesthetists (ANZCA), which includes the Faculty of Pain Medicine (FPM) and Chapter of Perioperative Medicine, thanks you for the opportunity to provide feedback on the above. ANZCA is the professional organisation responsible for the training and examination of anaesthetists and specialist pain medicine physicians and for the standards of clinical practice throughout Australia and Aotearoa New Zealand. ANZCA is committed to ensuring the highest standards of patient safety and care through excellence in anaesthesia, pain medicine and perioperative medicine education, training, and research.

The college has consulted with our national committees (National Committee NZ and FPM NZ) and education and policy advisors in Australia and Aotearoa; their feedback informs this response to the selected consultation questions that are relevant to the college's expertise.

Question 5

No.

ANZCA **does not support** a separate regulatory authority for natural health products (NHPs) and is disappointed that the protracted debate over NHPs continues to impact long overdue reform of the Medicines Act,1981. A single regulatory authority for therapeutic products, as defined in the Therapeutic Products Act 2023, (but subsequently repealed[1][1]) encompassing medicines, medical devices, NHPs and active pharmaceutical ingredients (APIs) would provide a coherent regulatory framework. Importantly, it would enable risk-based regulation to be applied consistently across products without safety assessments being influenced by, or conflated with, commercial interests and market development objectives.

The college questions whether facilitating industry development and export growth should be an objective of health product regulation, the primary purpose of which is to provide assurance about the safety, quality, and, where relevant, efficacy of products. A regulator's credibility depends on its independence from commercial objectives. Industry development, trade promotion, and export growth are important government objectives that we suggest are more appropriately pursued through trade and economic development agencies than through a health regulator.

The consultation material suggests that a key rationale for a new system is to remove barriers to exports, including for products that may otherwise meet the definition of a medicine. However, it is not clear that creating a separate regulatory regime for NHPs is necessary to achieve that objective. Regulatory recognition in international markets is generally enhanced by alignment with established international standards and regulators, rather than by creating a distinct domestic framework tailored to export promotion.

[1] *Therapeutic Products Act Repeal Act 2024*, Public Act 2024 No 55 (NZ). Accessed 2026 Oct 30. Available from: https://www.legislation.govt.nz/

In this context, we note that Aotearoa often accepts the Australia's Therapeutic Goods Administration (TGA) approvals for many of these products. There have been repeated attempts to formally harmonise the TGA and Medsafe, so far without success, though there is generally strong alignment in terms of health regulation, education and practice between the two counties.

One of the objectives referred to in the cabinet paper was to "*support industry development and exports while maintaining confidence in New Zealand's reputation as a manufacturer of quality products that are safe and suitable for their intended use would be to strength that connection*". We suggest that one of the best means of achieving this is to secure consistent regulation for therapeutic goods across both countries with a single regulatory authority like the TGA.

Question 6

Disagree.

Neither of the proposed objectives is fully aligned with the core purpose of a safety regulator. While enabling informed consumer choice and supporting access to NHPs are important considerations, there will be occasions where these objectives must give way to public health and safety concerns. In such circumstances, an independent regulator with the appropriate depth of scientific and regulatory expertise is needed to identify and respond to those risks. New Zealand's relatively small population and limited pool of specialist expertise indicates that regulatory capability is best concentrated within a single therapeutic products regulator rather than dispersed across multiple agencies.

Question 7

Disagree with Principles 1 and 2

Proportionality, fairness and efficiency are important features of good regulatory design, but these principles place significant emphasis on consumer access, choice, and compliance costs, rather than the primary purpose of regulation, which is the protection of public health and safety.
The references to consumer choice and timely access are particularly challenging in this context, because they introduce objectives that may, at times, conflict with public safety considerations, particularly given that New Zealand is one of only two countries to allow direct to consumer advertising of pharmaceuticals, the other being the USA. There is a risk of putting the regulator in an inherently conflicted position by requiring it to consider commercial and access objectives alongside its safety responsibilities.

Compliance costs and regulatory efficiency are also legitimate considerations in the design of a regulatory system, but they should not be elevated to a guiding principle for a health regulator whose role is to protect public health and safety through independent, evidence-based decision-making. Compliance costs should be proportionate to risk, rather than risk assessment being constrained by a desire to minimise compliance costs. Any requirement to minimise compliance costs or facilitate market access risks creating tension with that role, particularly where products raise concerns about safety, efficacy, or misleading health claims.

The college's concern is reinforced by the consultation material itself. The Questions and Answers document states that "supporting industry development and exports is a key objective for any new system" and seeks views on how regulation could better support access to international markets. While industry development and export growth are important policy objectives, they are fundamentally economic objectives. Promoting industry development, reducing barriers to exports, and facilitating market access are functions more appropriately performed by economic

development and trade agencies than by a health regulator. A regulator must be free to assess products solely on the basis of safety, quality, efficacy, and evidence, without being required to balance those considerations against commercial interests. Public and international confidence in NHPs products will be strengthened, not weakened, by a regulator whose primary and overriding objective is consumer protection.

Agree with Principle 3
The college strongly supports the third principle. Alignment with international regulatory practice, such as those outlined and compared in the 2024 Report by Sapere[2] promotes public confidence, supports regulatory efficiency, facilitates international cooperation, and helps ensure that New Zealand consumers are afforded protections comparable to those in other jurisdictions. A key objective for NHP regulation should be greater harmonisation with Australia's TGA and strengthening the already close trans-Tasman health relationship. Beyond improving regulatory efficiency and consistency, closer alignment would reduce unnecessary duplication for regulators and suppliers, support a more predictable regulatory environment, and increase consumer and practitioner confidence in regulatory decisions. It would also facilitate access to a wider range of appropriately regulated products, addressing a common source of frustration among health practitioners who are unable to access products available in Australia because of differing regulatory requirements and market constraints. A more harmonised approach would help create a more seamless trans-Tasman market while maintaining comparable standards of safety, quality, and performance for consumers in both countries.

Question 9
Should a future regulatory system include both edible and inedible natural health products (eg, creams and patches) that make health-related claims?

This question highlights the difficulties that a regulator will face. Determining NHP boundaries can be complex and multifaceted. A substance that presents minimal risk when applied as a cream may pose different risks when delivered via a transdermal patch, oral tablet, spray, or injectable product. A regulator focused solely on NHPs is unlikely to have the depth of expertise, comparative context, or oversight across medicines, medical devices, and other therapeutic products needed to determine where particular products sit within the wider therapeutic landscape, and to ensure that similar products are regulated consistently according to their risks rather than their marketing category.

Question 14

Rules for labelling are best developed alongside other therapeutic products to avoid confusion and ensure consistency. This would be more efficiently and robustly managed by a single regulator.

Question 18

Boundaries between NHPs, nutraceuticals, medicines, medical devices, and Rongoā Māori are often unclear, overlapping, or evolving. Determining the appropriate regulatory category for a product requires extensive scientific, clinical, and regulatory expertise, including knowledge of

[2] Sapere Research Group. *International approaches to natural health product regulation*. Wellington: Ministry of Health; 2024. Accessed 2026 Oct 30. Available from: https://www.health.govt.nz/system/files/2024-06/international_approaches_to_nhp_regulations.pdf

pharmacology, product claims, interactions with medicines, and potential effects on physiological systems such as blood pressure, coagulation, and gastric emptying.

Many products fit into a range of categories. Peptides, both naturally occurring and synthetic, for example, illustrate why regulatory boundaries can be difficult to define. Depending on their formulation, intended use, route of administration, and claims made about them, peptide products may be regulated as medicines, cosmetics, or nutritional supplements. Last year, in a Medsafe's submission to the Medical Classification Committee, Medsafe identified a wide variety of unscheduled peptides that are marketed as anti-aging and/or hair growth promotion products as well those developed for a range of therapeutic purposes, including (but not limited to) cognitive enhancement, hair growth, libido enhancers, sexual dysfunction, immune enhancers, and cancer treatments[3].

Australia's TGA has three classes of peptides:

- Therapeutic Goods (Schedule 4): Most synthetic, injectable, or targeted oral peptides (such as growth hormone secretagogues, BPC-157, TB-500, or GLP-1 receptor agonists) Prescription-Only Medicines.
- Cosmetic and Skincare Peptides: Topical peptides used in creams or anti-aging serums are regulated as cosmetics.
- Dietary/Nutrition Supplements: Certain basic food-derived peptide products—most commonly collagen peptides—are sold as general nutritional or dietary supplements.

The Schedule 4 peptides are of particular interest to ANZCA. GLP-1s and weight-loss peptides slow down digestion and equally slow down the emptying of stomachs ahead of surgery. These are regulated for prescription-only use and ANZCA has developed guidance for clinicians[4] and patients[5] on them, including fasting guidance[6].

However, in addition to the concerns about the risks to health posed by the proliferation of new/novel peptides raised by Medsafe (Medsafe, n.d.), a growing number of unapproved weight-loss peptides are reportedly being imported and marketed outside established regulatory pathways. The recent Victorian health alert concerning *retatrutide* demonstrates the risks that can arise when products with pharmacological effects are marketed without appropriate regulatory oversight[7].

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[3] Medsafe. (n.d.). *Classification of Unscheduled peptides* (Agenda item 5.7). Medicines Classification Committee. Accessed 2026 Oct. https://www.medsafe.govt.nz/profs/class/Agendas/Agen74/5.7Peptides.pdf

[4] Australian and New Zealand College of Anaesthetists (ANZCA). *GLP-1 receptor agonists: clinical practice recommendations*. Melbourne: ANZCA; 2024. Accessed 2026 Oct 30. Available from: https://www.anzca.edu.au/safety-and-advocacy/standards-of-practice/clinical-practice-recommendations-regarding-patients-taking-glp-1

[5] Australian and New Zealand College of Anaesthetists (ANZCA). *New GLP-1 agonist guidance FAQs and patient information*. Melbourne: ANZCA; 2024. Accessed 2026 Oct 30. Available from: https://www.anzca.edu.au/news-and-safety-alerts/new_glp-1_agonist_guidance_faqs_and_patient_information

[6] Australian and New Zealand College of Anaesthetists (ANZCA). *Fasting before your surgery*. Melbourne: ANZCA. Accessed 2026 Oct 30. Available from: https://www.anzca.edu.au/patient-information/about-anaesthesia/eating-and-drinking-before-your-surgery

[7]Victoria Department of Health. *Toxicity linked to unapproved peptide product labelled Retatrutide*. Melbourne: State Government of Victoria; 2024. Accessed 2026 Oct 30. Available from: https://www.health.vic.gov.au/health-alerts/toxicity-linked-to-unapproved-peptide-retatrutide

NHPs may move between, or share characteristics of, medicines, supplements, cosmetics, and other therapeutic categories. Effective regulation requires access to the full range of scientific and regulatory expertise available within a comprehensive therapeutic products regulator, rather than a regulator focused solely on NHPs.

Conclusion

The college is not sanguine that a separate regulator for NHPs would improve safety outcomes, reduce costs, or enhance market access, or New Zealand's reputation compared with regulation within a unified therapeutic products framework. We consider that:

- If the objective is **safety**, a single therapeutic products regulator makes sense.
- If the objective is **exports**, a regulatory objective is not appropriate
- If the objective is **harmonisation with overseas markets**, Aotearoa already draws heavily on international regulatory expertise and standards.

ANZCA appreciates the opportunity to provide feedback on the future regulation of NHPs and strongly **recommends** a single regulatory scheme for all therapeutic products, consistent with the approach adopted in the repealed Therapeutic Products Act, 2023. The Act recognised that medicines, medical devices, and NHPs should be regulated within a single framework "to ensure acceptable safety and quality standards throughout their life cycle and to provide consistent oversight of health claims made about those products".

Establishing a separate NHP regulator would fragment regulatory expertise and risk inconsistent decision-making across products with similar characteristics or risks. NHPs like other health products should be regulated according to their risks and claims, rather than the category in which they are marketed.

Nāku noa, nā





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