New Zealand Medical Association
Te Hauora mō ngā Iwi Katoa

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Michael A Pead
Chief Executive
Pharmacy Council of New Zealand
PO Box 25-137
Wellington 6011
By email: enquiries@pharmacycouncil.org.nz

Code of Ethics Review

"It would seem responsible for those working within the medical establishment to visibly distance themselves from treatments which cannot be understood, so that alternative medicine does not obtain vicarious legitimacy through some presumed resemblance or connection to medicine. This would have the positive effect of stemming the new wave of commercialized alternative medicine which exploits the good faith and finances of desperate patients"[1]

Dear Michael

The New Zealand Medical Association (NZMA) wishes to provide feedback on the above consultation. The NZMA is New Zealand's largest medical organisation, with more than 5,500 members from all areas of medicine. The NZMA aims to provide leadership of the medical profession, and to promote professional unity and values, and the health of all New Zealanders. One of our key roles is to publish and maintain the Code of Ethics for the New Zealand medical profession.[2] Our submission has been informed by feedback from our Advisory Councils, Ethics Committee and Board.

1. The focus of our feedback is on how the revised Pharmacy Council of New Zealand (PCNZ) Code of Ethics (the Code) addresses the sale of complementary and alternative medicines (CAMs). Wording changes relating to the promotion, supply and sale of CAMs in the Code were originally proposed in 2015 as part of a partial review of the Code. These proposed changes **removed** the need for the supply of complementary therapy or other healthcare product to meet the "credible level of evidence of efficacy" requirement. At the time, the NZMA strongly opposed these changes.[3] Following consultation, the PCNZ did not implement the proposed changes.

[1] Shahvisi A. No Understanding, No Consent: The Case Against Alternative Medicine. Bioethics. 2016 Feb;30(2):69-76.
[2] NZMA. Code of Ethics for the Medical Profession. 2014. Available from https://www.nzma.org.nz/publications/code-of-ethics
[3] NZMA Submission to Pharmacy Council on Proposed supplementary wording to clause 6.9 of the Code of Ethics 2011. 9 October 2015. Available from

2. The current review once again proposes changes relating to the sale of CAMs, as part of a full review of the Code. These changes are listed below.

Original clauses from 2011 Code	New and revised clauses in new Code
	New definition - therapeutic products: for the purposes of this Code the term refers collectively to medicines, as well as the wider range of products that are, or are represented as having been, manufactured for bringing a health benefit to users, including complementary and alternative medicines
Clause 1.7 Only supply a medicine, complementary therapy, herbal remedy or other healthcare product to a patient when you are satisfied that the patient understands how to use it safely and appropriately	**Clause 1g:** before recommending, supplying or promoting a therapeutic product, considers available evidence, supports the patient to make an informed choice and only supplies a product when satisfied that it is appropriate, and the person understands how to use it correctly
Clause 6.9 Only purchase, supply or promote any medicine, complementary therapy, herbal remedy or other healthcare product where there is no reason to doubt its quality or safety and when there is credible evidence of efficacy.	**Clause 4h:** ensures that when providing any therapeutic product or other healthcare product that the health and wellbeing of the patient is the primary consideration and that the benefit of use outweighs the risk **New clause 4hh:** ensures that the quality and safety of any therapeutic product or healthcare product supplied can be assured

We note that the above changes are accompanied by amendments to the PCNZ's statement and protocol on CAMs. We have included this entire statement and protocol in an Appendix for the benefit of our members. We understand that the PCNZ gives equal weight to its statements and the Code.

3. The net effect of the PCNZ's proposed revisions, even when taking into account the updated statement and protocol on CAMs, is a considerable weakening of the evidence requirements for CAMs compared with the 2011 Code. Of particular concern is the scrapping of Clause 6.9 requiring credible evidence of efficacy. While the replacement clauses 1g, 4h and 4hh do require a pharmacist to consider available evidence, ensure the health and wellbeing of the patient is the primary consideration, that the benefit of use outweighs risk, and that the quality and safety can be assured, these provisions, though welcome, do not suffice. While the updated PCNZ statement and protocol on CAMs provides expanded guidance on the expectations regarding CAMs, clause 13 permits the supply of CAM products that have no current evidence of proven efficacy.

4. While the PCNZ has sought alignment between the new Code and the Pharmaceutical Society of Australia's 2017 Code of Ethics, we note that the Australian Code retains the requirement for a credible evidence of efficacy.[4] We are interested to know the reasons why the PCNZ has opted to deviate from this particular clause and thus diverge from the Australian Code.

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https://www.nzma.org.nz/__data/assets/pdf_file/0006/44781/subPharmacy-Council-Proposed-Supplementary-wording-to-Code-of-Ethics.pdf

[4] Pharmaceutical Society of Australia. Code of Ethics for Pharmacists. Integrity principle 1, clause h (p14), February 2017. Available from https://www.psa.org.au/downloads/codes/PSA-Code-of-Ethics-2017.pdf

5. The NZMA remains strongly opposed to the changes relating to CAMs that are being proposed by the PCNZ in the revised Code. The use of credible evidence to inform and base decisions about healthcare is a core value of the NZMA.[5] This is true whether the decisions relate to policy or treatment. It is our view that CAMs, currently unregulated in New Zealand, are the antithesis of evidence-based medicine. In the following paragraphs, we elaborate on our opposition to the changes being proposed relating to the provision of CAMs.

6. We have major reservations with the PCNZ's proposal to include CAMs under the definition of 'therapeutic products'. We contend that doing so is misleading and confusing. The term 'therapeutic' has intrinsic connotations of effectiveness in treating a disease or alleviating a symptom, above and beyond the placebo effect. Furthermore, 'therapeutic product' is currently defined by Medsafe as products that have a therapeutic purpose, and is therefore captured under the Medicines Act, which explicitly regulates anything that is deemed to be for a therapeutic purpose.

7. The proposals are particularly concerning given the current lack of regulation of CAMs in New Zealand. By contrast, Australia regulates such products under the Therapeutic Goods Administration. Nevertheless, the Natural Health and Supplementary Products Bill is currently awaiting its second reading in New Zealand. When passed, the Bill will require that health benefit claims made for natural health and supplementary products be supported by scientific or traditional evidence. Despite pointing out various deficiencies with the accompanying regulations, we have welcomed the proposed requirement that all health claims for natural products **must** be supported by evidence.[6] It is our view that the proposed wording changes to the PCNZ Code of Ethics are at odds with the intent of this Bill.

8. We believe that the proposals under consideration will further contribute to the inappropriate legitimisation of CAMs by being offered for sale in dispensing pharmacies. The presence of these products on the shelves is likely to be perceived as an emphatic endorsement by a mainstream and trusted healthcare professional community. New Zealanders already have poor health literacy.[7] Many patients are unlikely to know the important differences between prescribed medications and CAMs.

9. Following a review of pharmacy regulation and remuneration by the Department of Health in Australia,[8] the perception of reliability and efficacy of CAMs based on the status of the pharmacy as a healthcare provider was identified as contributing to a risk of harm. With respect to homeopathy, the interim report states that:

> *The only defence put to the Panel regarding homeopathy was that it was harmless and able to be used as a placebo in certain circumstances. The Panel does not believe that this argument is sufficient to justify the continued sale of these products in pharmacies that supply PBS medicines. In particular, the Panel notes that the supply of homeopathic products through pharmacies is not benign but, rather, risks creating a perception of*

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[5] NZMA backs call for evidence-based policy making. Available from https://www.nzma.org.nz/news-and-events/media-releases/nzma-backs-call-for-evidence-based-policy-making; Where's the evidence? NZMA Digest, July 2016. Available from https://www.nzma.org.nz/advocacy/from-the-chair/wheres-the-evidence

[6] NZMA. The regulation of Natural Health Products. Submission to the Ministry of Health. 15 February 2016. Available from https://www.nzma.org.nz/__data/assets/pdf_file/0009/47079/NZMA-Submission-on-the-regulation-of-natural-health-products.pdf

[7] NZMA. Improving health literacy. Policy Briefing. March 2017. Available from https://www.nzma.org.nz/publications/improving-health-literacy

[8] Department of Health, Australian Government. Review of pharmacy remuneration and regulation. June 2017. Available from http://www.health.gov.au/pharmacyreview#InterimReport

reliability and efficacy in the mind of the consumer based on the status of the pharmacy as a healthcare provider. This may encourage patients to choose a homeopathic product over a conventional medicine with robust evidence of efficacy, which creates a risk of harm to the patient's health.

10. As valued members of the multi-disciplinary health care team, pharmacists have an important role in improving the health outcomes of all New Zealanders. The profession is regulated, has a rigorous scientific training and is increasingly seeking to operate at the top of scope by seeking to take on tasks such as prescribing and the provision of other complex services. Pharmacists should not, therefore, also be selling therapeutic products that are known to be ineffective. We believe that allowing them to do so is contrary to the profession's own aspirations, including of trustworthiness and professionalism. More broadly, it undermines the social contract between the public and the profession. The pharmacist is trusted by patients and other members of the healthcare team precisely because of their scientific training. The sale of products that pharmacists know do not work is inconsistent with the high trust healthcare professional the public expects and the profession requests.

11. Our interpretation of the proposed wording changes is that the weakening of evidence requirements for CAMs is inconsistent with several principles of the PCNZ Code, particularly principle 1 ("Make the health and well-being of the patient your first priority") and principle 6a ("Maintain contemporary knowledge of evidence-based practice"). The proposed changes are also at odds with the NZMA Code of Ethics, which states as an overarching principle that doctors must "adhere to the scientific basis for medical practice while acknowledging the limits of current knowledge and contributing responsibly to innovation and research". The proposed changes also risk undermining collaborative initiatives between pharmacists and doctors. We draw the Council's attention to the joint vision statement by the Pharmaceutical Society of New Zealand and the New Zealand Medical Association,[9] which states that "Both professions will support the stated codes and policy positions of the ethics of each and will seek alignment".

12. We note that the PCNZ states that amendments to its statement on CAMs are based on the patient screening tool in the Medical Council of New Zealand Statement on CAMs. It appears that the PCNZ has cherry-picked from the MCNZ Statement on CAMs, as the revised Code fails to include perhaps the most important sub clause of the MCNZ statement on CAMs. This sub clause states that when treating patients, doctors must "*ensure that the [complementary or alternative] treatment is efficacious, safe and cost-effective*".[10] We are aware that the MCNZ is currently consulting on a revised statement on CAMs. The requirement to ensure that a treatment is efficacious appears unchanged in the proposed revised statement.

13. The business model of community pharmacy in New Zealand entails the retail of various products in addition to subsidised dispensing of pharmaceuticals. It means there are serious conflicts of interest with the sale of CAMs in pharmacies. This is a further reason why we believe it essential to provide the public with the highest levels of ethical protection. We do not believe that it is acceptable for a pharmacist to dispense medications that are prescribed by a doctor while at the same time selling CAMs that they know lack credible evidence of efficacy. Co-locating CAMs and evidence-based medicines in pharmacies, with both categories being sold by

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[9] Pharmaceutical Society of New Zealand & the New Zealand Medical Association. Vision 2020 Partnership for Care: Pharmacists and Doctors Working Together. Available from https://www.nzma.org.nz/__data/assets/pdf_file/0004/37669/Partnership-for-care-2020-Pharmacists-and-Doctors-working-together-2014-Vision-Printer.pdf

[10] Medical Council of New Zealand. Statement on complementary and alternative medicine. March 2011. Available from https://www.mcnz.org.nz/assets/News-and-Publications/Statements/Complementary-and-alternative-medicine.pdf

pharmacists, gives inappropriate legitimacy to CAMs. It is worth noting that one reason that prescribing has traditionally been separate from dispensing is to protect against the harms and perverse incentives that can arise when both activities are undertaken by a single person.

14. While the suggestion to support a patient to make an informed choice with regard to CAMs seems attractive, this is not an adequate substitute for a credible level of evidence. We also question its feasibility, including how it would be implemented, monitored and enforced in a busy community pharmacy setting. Will pharmacists provide purchasers with systematically-derived scientific evidence of poor/nil efficacy for many complementary therapies they are selling, such as the evidence available in the Cochrane reviews? We also draw attention to issues such as publication bias, poor quality trials and regression fallacy, which are of particular relevance for complementary and alternative therapies.

15. We understand that the Code and Statement apply only to pharmacists. Yet many transactions in pharmacies occur between patients and pharmacy assistants or technicians. Oversight or operating procedures are not flagged in these documents. We believe that the practical challenges around oversight of these staff are another strong reason why CAMs supplied in a pharmacy should have credible evidence of efficacy.

16. We understand that patient autonomy and freedom of choice are being advanced as the rationale for the proposed rewording to the Code. We believe these are largely spurious arguments on which to remove the requirement for credible evidence of efficacy. Given the huge amount of marketing by the CAM industry, including TV infomercials, a massive imbalance in the volume and accessibility of public information on CAMs works in favour of the industry and against well-informed free choice by patients. Furthermore, CAMs are already available to people to purchase at other outlets, such as health food shops and supermarkets.

17. A recent paper in *Bioethics* concludes that informed consent—an essential enabler of patient autonomy—is not possible for 'alternative medicine' treatments, as they do not draw on plausible biological mechanisms.[11] Without understanding, or even the possibility of such understanding, the author argues that true informed consent is impossible. The author concludes that it is unethical for medical professionals to offer alternative medicine treatments. While the mechanisms of action for some conventional treatments may not yet be fully understood, such treatments do have posited causal narratives and explanations drawing on well-established scientific foundations. The same cannot be said of 'alternative medicine' treatments.

18. There is an important distinction that must be made between ethics and the law. While the law may allow for the sale of complementary therapies in pharmacies, this should not be conflated with the ethics of selling such products in pharmacies. Nor should ethics be used in an attempt to address a legislative or regulatory deficiency. We agree that it is not ideal for people to purchase complementary therapies via the internet, where they may lack sufficient information about the product and alternative treatment options. But amending the PCNZ Code of Ethics is not the appropriate means to address this—particularly when it leads to a weakening of the requirements for the supply of CAMs in pharmacies.

19. We draw attention to another recent paper in *Bioethics* that describes the significant ethical problems with the advertising and selling of CAMs.[12] The authors concluded that "*market interactions, in order to be considered ethical, need to involve products that actually work, that*

[11] Shahvisi A. No Understanding, No Consent: The Case Against Alternative Medicine. Bioethics. 2016 Feb;30(2):69-76.
[12] Macdonald C, Gavura S. Alternative Medicine and the Ethics of Commerce. Bioethics. 2016 Feb;30(2):77-84

are advertised honestly, and that do not have undue effects on innocent third parties. Many examples of CAM fail on one or even all of those counts".

20. We are also concerned at the impact of the proposed changes relating to CAMs on health equity.[13] Patients who are least likely to consult a doctor may end up being more likely to purchase costly 'healthcare' products from their pharmacy that do not work, when least able to afford these products yet most at risk of poor health outcomes. The proposal also undermines the wider health sector's efforts to improve health literacy. These are societal harms associated with the proposal. We note that the Pharmacy Council has an overriding duty to protect the public and promote good pharmacist practice. We also note that the Council's vision is 'Safe Effective Pharmacy Practice'. It is our view that the proposals are counter to the Council's duty and vision.

21. Finally, we suggest that the PCNZ consider moving from a position of non-maleficence to beneficence. This would mean not just doing no harm (which is sometimes advanced as a justification for CAMs) but actually doing good (which moves to doing things that have an evidence base). It would mean the Council would be holding the profession to account and taking a position of no tolerance for non-evidence based products / treatments. We believe this would be in keeping with the professionalism expected of an important and trusted healthcare profession.

22. In summary, we do not support the proposed changes relating to CAMs. We believe that they represent a considerable weakening of the evidence requirements for CAMs compared with the 2011 Code. We would like to see pharmacists end the sale of complementary therapies or other healthcare products for which there is no credible evidence of efficacy. We urge the Council to, as a minimum, retain the wording of the original Clause 6.9 in the revised Code (which is included in the Pharmaceutical Society of Australia's 2017 Code of Ethics).

We hope that our feedback has been helpful and would welcome the opportunity to engage further with the PCNZ on this important consultation.

Yours sincerely

Dr Kate Baddock
NZMA Chair

[13] NZMA. Health Equity. Position Statement. 2011. Available from https://www.nzma.org.nz/__data/assets/pdf_file/0016/1456/Health-equity-2011.pdf

Appendix: Pharmacy Council Complementary and Alternative Medicines -Statement and Protocol for Pharmacists (revised July 2017)

Background information

1. Complementary and alternative medicine (CAM) generally refers to a broad set of health care and medical practices (e.g. acupuncture, herbal medicine) that are not currently an integral part of conventional medicine. CAM is also increasingly referred to as 'integrative medicine' or 'integrative health'. CAM treatments are typically used by patients in addition to conventional medical treatments, but in some instances, people use them instead of standard medical treatments.

2. CAM also includes 'complementary medicines' (CMs) or 'natural health products' (NHPs). These are pharmaceutical-type products that typically originate from natural sources, such as herbal medicines, homoeopathic remedies, and dietary supplements, as well as preparations used in traditional medical systems, such as traditional Chinese medicine (TCM).

3. CMs/NHPs are available in a range of forms, including as manufactured, processed, formulated products, and as crude fresh or dried material, often supplied to patients following a consultation with a natural-health practitioner.

4. It is also important to recognise that Rongoā Māori (traditional Māori healing) is categorised within these products. However, it is important to recognise that there are associated rights for Māori with these materials that will need to be considered, that extend beyond other CMs or NHPs.

5. In New Zealand, CMs/NHPs currently are subject to only weak regulations. For the most part, herbal and homoeopathic medicines are exempt from the requirements of the Medicines Act, and most CMs/NHPs fall under the Dietary Supplement regulations (under the Food Act), which provides some restrictions on ingredients, does not allow therapeutic claims, and does not require products to meet pharmaceutical quality standards.

6. The proposed Natural Health and Supplementary Products Bill seeks to regulate low risk NHPs in New Zealand; it defines a natural health product according to how the product is consumed, its ingredients, and the type of health claim made for the product. The proposed Bill will not regulate natural-health practitioners.

7. Draft proposals state that the Bill will require several steps to be completed before marketing CMs or NHPs, which is likely to enable both retailers and patients to confirm product quality and provide access to acceptable scientific or traditional use evidence to support health claims.

8. As medicines experts, pharmacists are expected to provide accurate, unbiased information to patients on the quality, use, safety and effectiveness of all medicines, including CMs/NHPs.

9. Few therapies have attracted more debate and controversy than homeopathy.[1] Homoeopathy has caused much debate in scientific literature with respect to its plausibility and practice, and lack of definitive evidence of efficacy for homoeopathic remedies. Even so, many people, including some healthcare professionals, continue to use or practise homoeopathic medicine and advocate its safety and efficacy.[2]

Best Practice Expectations for Pharmacists supplying CMs or NHPs

10. It is not the Pharmacy Council's (Council) purpose to endorse any particular CMs/NHPs or CAM treatment or practice; however, Council believes it is necessary that pharmacists have a basic knowledge of CAM and CMs/NHPs in order to engage with and advise patients appropriately. This also ensures pharmacists can meet their duty of care to patients and the profession.

11. Pharmacists should be able to counsel patients about the quality, general use, the current state of the evidence and any safety issues regarding CMs/NHPs, including their use and potential interactions with other medications. Where CMs/NHPs have demonstrated benefits for the patient and have minimal risk of harm, and where patients have made an informed choice and given their informed consent, Council does not oppose their considered use.[3]

12. The Pharmacy Council Code of Ethics requires that pharmacists maintain competence relative to their sphere of activity or scope of practice, which may include offering advice on treatments or medicines, including CMs/NHPs. Pharmacists selling or supplying CMs/NHPs must only recommend a product where they are satisfied of its safety, quality and effectiveness. They must explain the options available, including the risks and benefits, and assist patients in making informed decisions by providing relevant and independent information.

13. When supplying products or information about treatments/products that have no current evidence of proven efficacy pharmacists are expected to:

> 13.1 ensure that patients are informed about the degree to which treatments or products have been evaluated, and the degree of certainty and predictability that exists about their efficacy and safety

14. Pharmacists must advise patients when scientific support for treatment is lacking.

15. Pharmacists should be aware that some patients may stop using, or change their use of, prescription medicines if they think their health is improving due to their use of CMs/NHPs or CAM treatments. Patients should be encouraged to continue taking their prescribed medication, and to inform the prescriber of their use of CMs/NHPs. Where pharmacists encounter patients who are inappropriately self-treating with CMs/NHPs, they should provide appropriate advice and/or refer them to another health professional.

Steps that must be followed by pharmacists during consultations regarding complementary medicines/natural health products where a patient actively seeks advice or a CM/NHP is recommended.

16. You must obtain a patient medical history that meets the standard of competence required for the profession and that collects information regarding the patient's current symptoms, medical conditions, previous and current therapies, particularly conventional prescription and non-prescription medicines, and CMs/NHPs. You must advise patients of the evidence-based conventional treatment options, as reflected by current knowledge.

17. During a patient consultation for CMs/NHPs, in order to assess whether supply is safe and appropriate for a patient you must:

> 17.1 ensure that the proposed product is sourced from a reputable supplier and that the patient is not likely to experience harm from its use

17.2 ensure that the use of a CM or NHP will not cause patient harm by delaying or refusing access to accepted conventional medical treatment

17.3 have current knowledge about the therapeutic risks and benefits of the CM/NHP and discuss these in an appropriate manner with the patient

17.4 make the health and well-being of your patient the first priority

17.5 provide sufficient information regarding the CM/NHP to allow patients to make informed choices

17.6 not misrepresent information or opinion. Patients must be made aware of the likely effectiveness of a given therapy according to recognised peer-reviewed medical publications, in spite of your personal beliefs

17.7 provide the patient with a timeframe for accessing conventional medicine if their condition is unresolved or there is no improvement

When patients actively request supplies of CMs/NHPs from a pharmacist or self- selects product from the pharmacy:

18. The pharmacist, as a health professional has a duty of care to engage and attempt to initiate conversation around safe use of the CM/NHP or referral for conventional treatment when risk of patient harm is perceived. It is appreciated that not all patients will wish to engage in conversation when purchasing a familiar self-selected CM/NHP

18.1 Pharmacists should make efforts to monitor patients' self-selected use of CMs/NHPs from the pharmacy and engage in discussion with the patient whenever supply may not be in the patients' best interests.

References

1. Ersnt E. A systematic review of systematic reviews of homeopathy. Br J Clin Pharmacol. 2002 Dec; 54(6): 577–582.
2. Johnson T, Boon H. Where does homeopathy fit in pharmacy practice? Am J Pharmaceutical Education 2007 Feb 15; 71(1): 07.
3. Medical Council NZ Statement on complementary and alternative medicine. March 2011.

Acknowledgements

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Barnes J, McLachlan AJ, Sherwin CMT, Enioutina EY. Herbal medicines: challenges in the modern world. Part 1. Australia and New Zealand. Expert Review of Clinical Pharmacology 2016; 9(7):905-915,
Pharmacy Council acknowledges the patient assessment tool included in the Medical Council "Statement on complementary and alternative medicine"[3]