

8 October 2015

Dr Andrew Bary, Chair, Pharmacy Council of New Zealand PO Box 25137 Wellington 6011 via email: <u>consultations@pharmacycouncil.org.nz</u>

Dear Andrew

Proposed supplementary wording to clause 6.9 of the Code of Ethics 2011

The Pharmaceutical Society of New Zealand Inc. (the Society) is the professional association representing over 3,000 pharmacists, from all sectors of pharmacy practice. We provide to pharmacists professional support and representation, training for continuing professional development, and assistance to enable them to deliver to all New Zealanders the best pharmaceutical practice and professional services in relation to medicines. The Society focuses on the important role pharmacists have in medicines management and in the safe and quality use of medicines.

Thank you for the opportunity to submit comments on the proposed supplementary wording to clause 6.9 in the Pharmacy Council's Code of Ethics 2011.

We understand from the consultation document that the Pharmacy Council proposes to change the current wording of obligation 6.9, which reads:

"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."

to the following proposed supplementary wording in two parts:

6.9a "Only supply or promote any medicine or herbal remedy where there is no reason to doubt its quality or safety and when there is credible evidence of efficacy."

6.9b "Only supply any complementary therapy or other healthcare product where there is no reason to doubt its quality or safety and when sufficient information about the product can be provided in order for the purchaser to make an informed choice with regard to the risks and benefits of all the available treatment options."

The Pharmacy Council Code of Ethics is a key document that (as described in the Code):

- identifies the basic moral commitments of pharmacy care and serves as a source of education and reflection
- serves as a basis for pharmacists to monitor their own ethical conduct and that of their colleagues
- provides guidance for assessing the minimum ethical conduct expected of pharmacists

THE PROFESSIONAL VOICE OF PHARMACY

The Society supports any attempt to provide further clarity to wording or intent within the Code of Ethics, so that pharmacists clearly understand their obligations under the Code. In providing clarity, pharmacists will have a greater understanding of their obligations, while the Council will also have a clear guide as to when breaches of the Code occur, and can act accordingly.

The Society **does not support** the proposed supplementary wording in obligation 6.9 as the split wording in the two parts separates the therapy terms "medicine or herbal remedy" in 6.9a from "complementary therapy or other healthcare product" in 6.9b. The result is that the subsequent obligation attached to those therapies does not apply to the other.

To clarify further, "credible evidence of efficacy" is only required when supplying or promoting a "medicine or herbal remedy" (Obligation 6.9a), and "no reason to doubt... quality or safety and when sufficient information about the product can be provided" only applies to "any complementary therapy or other healthcare product.

The Society considers that the obligations of "credible evidence of efficacy" and no reason "to doubt... quality or safety" should apply to the supply or promotion of **all** therapies and products – ie. any medicine, herbal remedy AND any complementary therapy or other healthcare product.

The Society also considers that "sufficient information about the product" **must** be provided in order for purchasers to make an informed choice with respect to efficacy of that product and the risks and benefits of that against other treatment options.

In addition to commenting on the wording of the obligations, The Society has serious concerns about the definition and application of the phrases in the obligations in practice.

Pharmacists must comply with the Code of Ethics

The Council have stated that it is not the purpose of the Code, or the Council, to endorse or prohibit the supply of any particularly complementary and/or alternative medicine, product or practice. However, as the responsible authority for pharmacy under the Health Practitioners Competence Assurance Act 2003, standards of ethical conduct set by the Council must be observed by pharmacists. Indeed, in the Code of Ethics the Council requires that pharmacists must comply with "all the implied requirements of ethical practice" within the Code.

The Medicines Regulations 1984 (in Schedule 2 related to applications for a licence to operate a pharmacy) also refers to how pharmacists being employed or engaged in duties in a pharmacy are

"not requested or required to act in a way that is inconsistent with the applicable professional or ethical standards of the pharmacy practice"

Therefore, the obligations within the Code of Ethics must be interpreted clearly so that pharmacists have a clear understanding of what is considered ethical practice, but also so that the Council can investigate and act upon breaches of the Code.

Definition and interpretation of obligations

The wording of the proposed obligations 6.9a and 6.9b make reference to "credible evidence of efficacy" and "quality and safety". Therefore, if presented with a complaint against a pharmacist claimed to be in breach of the obligations within the Code of Ethics, the Council is expected to determine what is "credible evidence of efficacy" and/or "quality or safety".

The Society recognises that the application of a principles-based Code of Ethics to individual scenarios or circumstances is open to interpretation and challenge. Such scenarios are often

not "black and white", but "shades of grey" where a group of peers may have differing opinions to the acceptability or otherwise of a particular practice. It is expected that such "shades of grey" will always exist in pharmacy practice, as indeed it does in medicine and other areas of professional practice. However where a particular practice is determined to be unethical or unacceptable, this must be made clear. This is a difficulty faced when considering the evidence and use of complementary treatments against regulated medicines.

Complementary/alternative medicine: natural/herbal remedies

The Society recognises the history of pharmaceuticals, and indeed of the pharmacy profession, where the first "medicines" were derived from natural products. Many of these have been purified, refined and further manipulated in the development of modern day pharmaceutics. Much of modern pharmaceutical research continues to analyse the therapeutic potential of compounds found in naturally occurring substances derived from flora and fauna. We also recognise how the levels of evidence of the therapeutic benefits (or otherwise) of natural products can vary markedly, but understand the science behind their potential mechanisms of action has the same pharmacological basis as pharmaceuticals.

The Society supports the obligation of pharmacists that they should only supply or promote any complementary or 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. However, in cases where there is no credible evidence of efficacy (or quality or safety, but we will focus on efficacy for the remainder of this submission), then should we expect such practice by pharmacists to be, by definition, unethical?

Homeopathy

We note the Council's own 'Complementary and alternative medicines – best practice guidance for pharmacists' document makes reference to the Natural Health and Supplementary Products Bill which states:

"currently there is no accepted scientific evidence for the effectiveness of homeopathy and therefore that health benefit claims should not be made for homeopathic products"

This aligns with further documents and statements issued internationally, including the Australian National Health and Medical Research Council (NHMRC)⁽¹⁾, the Cochrane Library and others have noted homeopathic products show no effects beyond placebo. A number of government committees, professional pharmacy and medical organisations internationally have issued statements reinforcing this lack of effectiveness of homeopathy in treating health conditions. The Pharmaceutical Society of New Zealand does not at this time have a position statement on complementary medicines or homeopathy.

Homeopathy is not herbalism, and homeopathic science is not consistent with currently accepted medical and pharmacological science. Some pharmacists, and indeed other health professionals, have argued for the role of homeopathy as a valid form of treatment to meet patient demand, while acknowledging any "benefit" is achieved through a placebo effect, while not necessarily agreeing with the purported science behind homeopathic practice.

The question for the Council must then be whether it is considered ethical practice for pharmacists to charge a fee for products for which there is no accepted scientific evidence for effectiveness; OR for which they acknowledge the lack of evidence yet sell for the purposes of providing a placebo effect.

While we again note that the Council have expressed that it's not their purpose or the purpose of the Code of Ethics to "endorse any particular complementary or alternative medicine or practice", in setting the requirements for pharmacists to conform with obligation 6.9 (or 6.9a and 6.9b), the Council must determine whether the practice of homeopathy is consistent with the Code. Particularly when having homeopathic products available alongside pharmaceutical

medicines, or indeed herbal/complementary medicines with their varied levels of evidence, potentially implies clinical benefit *by association* and provision through a respected and regulated health professional.

The Council have endorsed the concept of the 'Eight Star Pharmacist' in the Competence Standards for the Pharmacy Profession. This also includes reference to pharmacists as decision-makers and

the appropriate, **efficacious**, safe and **cost-effective use of resources** (for example, personnel, medicines, chemicals, equipment, procedures, practices) should be the foundation of the pharmacist's work. (emphasis added)

Credible evidence of efficacy, quality and safety of pharmaceuticals

We must also recognise that the evidence for the efficacy of pharmaceutical medicines is often conflicting, varied and does change with time and clinical experience of using the medicine. Indeed the concept of "numbers needed to treat" implies that any given medicine will only work for a select number of mostly unidentifiable patients. Similarly, "numbers needed to harm" provides an indication that any given product may not be safe for all.

Regarding quality and safety of medicines, when a medicine is licensed and approved for use in New Zealand by Medsafe, we assume that the appropriate checks are evaluated and approved on our behalf. A similar process is expected for complementary/alternative therapies once the Natural Health and Supplementary Products Bill is passed by parliament. However, there is an increasing use of unapproved ("section 29") medicines being prescribed, particularly since Pharmac commenced funding a selection of these. We have no evidence of quality and safety of these products available, and no awareness of what checks are made by Pharmac when bypassing the role of Medsafe in approving funding. While pharmacists are not able to supply unapproved medicines without a prescription, what are the ethical obligations for pharmacists under 6.9 in this setting?

Concluding remarks

In setting the profession's Code of Ethics, pharmacists need assurances that questions of what is and what is not considered ethical practice will be determined by the Council. The Society acknowledges that many practice situations present challenges in how to apply the principles and obligations of the Code, and opinions between peers may differ. Where these opinions differ, or where a practice does not meet ethical obligations, The Council must provide a clear determination of what is ethical practice; particularly where there is a potential to affect the health, safety or wellbeing of patients.

Thank you for consideration of this submission.

Yours sincerely,

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1. National Health and Medical Research Council of Australia (NHMRC). NHMRC Information Paper: Evidence on the effectiveness of homeopathy for treating health conditions [Internet]. Canberra: National Health and Medical Research Council; 2015. Available from: https://www.nhmrc.gov.au/guidelines-publications/cam02