



From the Chair and Chief Executive

Talofa

Key topics discussed by Council at its June 2019 meeting included:

- A Council statement on electronic cigarettes / vaping – the statement is on our website.
- Recertification requirements for competence assurance – discussed further in a separate article but Council wishes to consider whether an alternative approach can be practically applied and provide the public greater assurance.
- Pharmacist prescriber qualification – considered and Council removes the Postgraduate Diploma in Clinical Pharmacy as a prerequisite for prescriber scope but all other prerequisites remain.
- Discussing the analysis undertaken on the last three years of Health & Disability Commission cases as they relate to pharmacy and whether it helps identify areas of regulatory focus.
- Considering the competence standards mapping work based on survey results and how different subsectors of the profession see / use the competency standards.
- Strategic plan, business plan and budget for 2019/20. Council has refreshed its five-year strategy and will soon issue an update that provides direction and framework for its work programme. Two key objectives:
 - Minimise risk of harm to public from pharmacist practice.
 - Maximise pharmacists' competence and fitness to practice.
- Council will be proposing an increase just under 1 percent (0.88%) for the April 2020 to March 2021 annual practising certificate fee. A consultation document will be released in August 2019, pending finalising 2018/19 end of year accounts. Council's strategic plan will be released as part of the Consultation document.

It is with regret that we advise Iain Buchanan has resigned from Council. Iain had indicated that he would not be seeking re-appointment in the latest process and has been waiting for a successor to be appointed but Iain has indicated he must now resign and return to his full commitment to the care of his patients in Whangarei.

Council has been deeply appreciative of Iain's expertise and experience as a community pharmacist. His unwavering focus on patient safety and the provision of high-quality health care has been central to the discharge of Council's duties. We understand that it is likely that the Minister will be finalising Council member appointments in the next month.

Ensuring public wellbeing through safe pharmacist practice

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Jeff Harrison
Chair



Michael Pead
Chief Executive

Prescriber qualification programme prerequisite removed

Council has completed the research phase of its review of the pharmacist prescriber qualification. A report provided to Council by an external expert included consideration of the Council requirement for the Post Graduate Diploma in Clinical Pharmacy as the course entry prerequisite.

After consideration of information from the project report, Council has removed its requirement for completion of a postgraduate Diploma in Clinical Pharmacy prior to entry into the postgraduate certificate in pharmacist prescribing. The guidance statement published by Council in 2012 signalled that a review of the necessity for the prerequisite diploma would occur. There was always an acknowledgement of the potential for a prerequisite to create a barrier to registration. The report provided to Council acknowledges different opinions about the value of the diploma prerequisite. It provides reasons for Council's decision, the most significant being that there is no essential learning for the pharmacist prescriber competencies that is uniquely covered in the diploma programme.

We continue to require at least two years of post-registration experience in collaborative patient-facing practice that is relevant to the area of practice in which a pharmacist plans to prescribe. Council appreciates that pharmacists may come to the prescribing programme from a wide range of qualifications and practice experience, and that some may need additional preparation to increase their likelihood of success in the programme.

There is an expectation that pharmacists will discuss their experience with the universities to establish whether additional actions may assist in their success. We expect universities to be enabling without applying unnecessary barriers to the qualification.

Council has published a new [guidance statement](#) outlining requirements for registration in the prescriber scope which is now available on the Council website.

The Heads of Schools of Pharmacy have been advised and are aware of Council's expectations to consider the background of pharmacists applying for entry into the prescribing course.

Media statement is available [here](#).



Melatonin Reclassification Process

Council knows that pharmacists are eager to learn what is required in order to supply melatonin to patients without a prescription.

On 24 June 2019 melatonin was reclassified as:

Gazette notice:

Prescription Medicines

Melatonin; except when supplied in medicines for oral use containing 3mg or less per immediate release dose unit, or 2mg or less per modified release dose unit, when sold in the manufacturers original pack that has received consent from the Minister of Health or the Director General for the treatment of primary insomnia for adults aged 55 years or older for up to 13 weeks by a registered pharmacist.

We would like to explain the new Council process for reclassification of medicines, which came into effect for reclassification proposals submitted to Medsafe after March 2019.

[Council's process](#) is now integrated into the final pages of the Medsafe document [How to change the legal classification of a medicine in New Zealand \(March 2019\)](#).

In future, proposals submitted to Medsafe to reclassify medicines for supply by pharmacists will be reviewed in accordance with the Council process first, and a report presented to Medsafe's Medicines Classification Committee (MCC) for consideration at the same time as the proposal submitted by any organisation/person.

Both Council and the Society will review the proposal against their [joint reclassification framework](#) to determine whether any additional training is required or whether pharmacists already have the necessary competencies to supply the medicine. This process was put in place after acknowledgement that Council, in its role under the Health Practitioners Competence Assurance Act 2003, is best placed to determine whether pharmacists are competent to supply a medicine without a prescription. Not all reclassifications require training and Council is focussed on ensuring pharmacists are not over-regulated unnecessarily. There will be circumstances where some additional professional development or training may be necessary to ensure all pharmacists are utilising consistent, evidence based, clinical decision making tools when considering the provision of a medicine that has been reclassified for pharmacist supply.

The melatonin proposal was submitted to Medsafe for reclassification before the new process was implemented. We therefore had to await publication of the final gazette notice wording (24 June 2019) before finalising the Council requirements. Ideally therefore, in future Council will have sufficient time to determine any professional development or training requirements as part of the reclassification process. Council will then be able to time the release of its requirements in alignment with the publication of the Medsafe gazette notice.

The process for melatonin is now in its final stages and publication of the Council requirements will be on our website on 1 August 2019.

FOLLOW YOUR GUT INSTINCT:

Pharmacists felt something was not right

More than once, we pharmacists have said (or heard other pharmacists say) that we've identified a near miss on a prescription that protected the patient from harm because we "had a 6th sense about it".

Recent Health and Disability Commissioner (HDC) cases reviewed by the Pharmacy Council involve pharmacists who identified that a dispensing error happened because they did not follow through with their gut instinct.

Case 1: A pharmacist was interrupted in the middle of their final check when they were following up on an issue based on a gut instinct. The pharmacist returned to the prescription and thought they had already addressed the issue, carrying on with the rest of their checks and signing off the prescription.

Case 2: A pharmacist was unsure of the instructions on a prescription and had the gut instinct to clarify this with the doctor.

The pharmacist checks the instructions with the child and caregiver. The child appears familiar with the medicine and the caregiver assures the pharmacist that the child's mother knows about the medicine. Although the pharmacist was still unsure of the instructions on the prescription, they provided the medicine based on assurance from the child and caregiver.

Learning points

The pharmacists have reflected on their dispensing errors and learned from them by:

- Not letting a busy period affect their **dispensing, accuracy** checking, and **clinical** checking procedures
- Having a **staff discussion** about the dispensary workflow to help **minimise interruptions** during the pharmacists' final check
- Always **following your gut** instinct and making sure you are confident with what you are giving out
- **Signing next to each script** to note that the final accuracy and clinical check has been done.

If it's a feeling about a person, again acting on that gut feeling could help someone who needs that extra bit of help that you've sensed, or it could help stop something worse from happening.

Thoughts from an experienced pharmacist.....

Often when you have a feeling that something is not right, it generally is not. Following your gut instinct can help sort the issue or prevent serious harm from occurring. So, listen to that feeling, check it out. Do not defer it due to being busy or by thinking that it's not important.

COMMUNICATION

Patients under Opioid Substitution Treatment

The Pharmacy Council has recently received complaints and concerns relating to pharmacists' treatment of patients under Opioid Substitution Treatment (OST).

A common theme was that patients did not believe they had been treated with respect, were not being fully informed about the pharmacy's opioid substitution processes and felt they had been discriminated against.

We can aim to reduce communication barriers by listening to our patients and treating all patients with respect. It is important we are aware that our own perceptions and that of others' plays a part in how the messages we convey are understood.

Exercise

We encourage pharmacists to personally review their communication with methadone patients to ensure that patients are provided with appropriate and respectful responses to their queries or concerns regarding the service you provide.

This is a good opportunity to **review and discuss your Standard Operating Procedures for OST** to ensure they meet all legal, regulatory, professional, ethical, cultural and contractual requirements.

Competence Standards

M1.1.4: Treats others with sensitivity, empathy, respect and dignity.

M1.6.5: Communicates decisions comprehensively including the rationale behind the decision.

M2.1.5: Assesses an individual's understanding before providing information.

O3.5.1: Assesses patients' needs and knowledge of prescribed medicines, including Pharmacist Only Medicines, to identify when additional information and education is required.

Code of Ethics

2B Recognises and respects patients' diversity, cultural knowledge and skills, gender, beliefs, values, characteristics and lived experience, and does not discriminate on any grounds.

UPDATE

Recertification Update

We signalled some time ago that Council is undertaking a review of how it assures the public of pharmacists' competence for their practice of pharmacy. Assurance is provided by compliance with our annual recertification requirements.

We recently completed the first phase of this review, looking at trends in the recertification thinking of health profession regulators in New Zealand and overseas, along with rationales for change. In June 2019, Council agreed that stronger assurance of pharmacists' ongoing competence should be provided to the public, in accordance with the Health Practitioners Competence Assurance Act (Part 3, s41). It has approved an approach for updating the existing recertification framework and we are now beginning the second phase of this important work.

We have reflected on our experience of and learnings from Council's current and previous frameworks. We have had initial conversations with pharmacists from different types of practice and we have heard a range of views in meetings held last year with pharmacists around New Zealand. We have also taken account of the profession's participation in continuing professional development (CPD) in recent years.

CPD has been a cornerstone of Council's requirements since 2004 and it will remain an important component of recertification. Regulators everywhere are responding to greater public scrutiny and accountability and like many others we have come to recognise that self-selected CPD no longer provides enough assurance on its own that a pharmacist is taking effective action to maintain or develop their competence.

Council has agreed on the principles and broad approach for updating the current recertification framework. A group of community and hospital pharmacists will be established to assist us in developing a framework that is effective and achievable.

We will continue to hold an individual pharmacist accountable for taking appropriate action to maintain their competence. Council now seeks greater surety that a pharmacist's professional development activities have been effective, ie they result in competence that is demonstrated in their own workplace.

We anticipate some departures from the current framework to reduce complexity and increase a focus on competence - including moving away from points' totals and three-year requirements.

We acknowledge that pharmacists want recertification requirements to be relevant to them and their practice of pharmacy, and effective without being onerous. We will focus firstly on requirements for patient-facing or patient-impactful pharmacists.

Technology requirements to support a new framework will be considered once the framework has begun to take its final form.

We are excited to move into the next phase of this development work, and we look forward to bringing pharmacists along with us towards giving the public greater assurance of their competence across different roles throughout their careers. We will continue report our progress through Council newsletters over the coming year.



Council expectations for Clinical Pharmacists in General Practice

Council has published a [Statement](#) outlining competence expectations of pharmacists practising in the General Practice environments in clinical roles. This statement originated from work completed in 2018 on a Code of Practice, as part of the Role of the Pharmacist project.

Council is frequently asked what skills pharmacists need to undertake clinical roles in general practice. We have utilised research from a working group of pharmacists and General Practitioners working collaboratively to identify the competencies considered fundamental to safe practice in this area.

Resource material developed by pharmacists to assist in the integration of colleagues into general practice has been collated by the Clinical Advisory Pharmacists Assn (CAPA) into a [Toolkit](#), which can be freely accessed from the CAPA section on the Society Website. This material will also be made available to general practice through the NZ Royal College of General Practitioners.

Council expectations of pharmacists on the use of electronic cigarettes/vaping for smoking cessation

The Pharmacy Council is aware that the use of electronic cigarettes (vaping) is becoming increasingly prevalent and that the Ministry of Health has recently publicised its position on vaping. In response to this, the Council has produced a [Statement](#) outlining its expectations of pharmacists regarding electronic cigarettes/vaping products for smoking cessation.



Health Practitioners Disciplinary Tribunal Decision

In February 2019 charges laid against Mr El-Fadil Kardaman before the Health Practitioners Disciplinary Tribunal (HPDT) were found.

These charges related to his repeated failure to fulfil his recertification obligations and to complete a competence programme. A precis with a link to the full HPDT findings may be found [here](#).