

Message from the Chair

Welcome to the March edition of the Pharmacy Council of NZ newsletter. It's hard to believe that we are approaching the end of the first quarter of 2013.

Competence and fitness to practise

At this time of year, our team are very busy processing annual practising certificate (APC) applications. When Council issues an APC to a pharmacist, it relies on information that has been declared and is a critical mechanism under the HPCA Act to assure the public that the pharmacist is competent and fit to practise. Council is also responsible for setting recertification programmes for the purpose of ensuring that pharmacists are competent to practise within their scope of practice. In this issue, we talk about the changes to recertification requirements for issue of an APC. I am confident that the new framework will provide greater flexibility and opportunities for pharmacists to demonstrate that they are maintaining their knowledge.

HPCA Review

The review of the HPCA Act is about to enter a second round of consultation in mid-March. Council provided a detailed submission in the initial consultation round and will again be prepared to comment on any proposed changes to the Act. Recommendations from the review, if implemented, could influence health regulation in New Zealand. The date for final advice to Cabinet will be July 2013

Regulatory Authorities Collaboration

Good progress has been made on the development of a Detailed Business Case (DBC) for the proposal that the RAs collaborate across all their functions. The Project Team comprising the RA Steering Group and PricewaterhouseCoopers project team are working well and, while there is much to do, they are on-track to deliver the DBC to regulatory authority Chairs for decision on the 15th April.

Thanks!

Finally, I'd once again like to acknowledge Council staff and my fellow Councillors for their tremendous contribution to the operations of Council.

Pharmacy Council Mandate

It appears there may be some confusion within the profession and the public arena about the role of the Pharmacy Council. Briefly the Council was established under the Health Practitioners Competence Assurance Act (HPCA) in 2004. The Council's mandate under the Act is clearly stated in Section 118, the underpinning philosophy of which is to protect the public and promote good pharmacist practice.

In addition to the functions of accrediting programmes, setting standards for entry to the profession, and CPD programmes for recertification, the Pharmacy Council must, under the Act, respond to information it receives relating to the fitness to practice or competence of a pharmacist and take action when required. Occasionally we do receive information or complaints outside of our mandate and in these situations we refer to the appropriate body.

We welcome your enquiries if you are uncertain whether the Council is the relevant body for your complaint. Please contact us to discuss your concerns or if you would like clarification on any issues affecting pharmacy practice.

Council in Good Hands

At the first 2013 Council meeting Dr Andrew Bary, Chairperson, and Mr Mark Bedford, Deputy Chair, were unanimously reappointed to their respective positions. These appointments provide a valuable continuity of leadership which, combined with the current skill and talent base already on Council, ensures the regulation of the pharmacy profession is good hands.

APC Renewal

Thank you to those who have already sent in annual practising certificate renewal applications.

Please allow a minimum of 10 working days for your application to be processed and an APC to be issued. If you require a hard copy of your new APC by 1 April 2013 your application should be at the Pharmacy Council office by Friday 15 March. However, as long as your application and payment are received by 31 March 2013 you are deemed to hold an APC, unless you are notified otherwise.

It is your obligation to ensure the information on your APC renewal application is correct. Please remember that the declaration you sign is legally binding and that providing false or misleading information may result in action and/or cancellation of your APC.

Health Practitioner Index-Common Person Numbers (HPI-CPN)

The Council has recently received a number of inquiries from pharmacists looking for their Health Practitioner Index-Common Person Number (HPI-CPN) for Exceptional Circumstances or PHAM applications. This number is printed on your Annual Practice Certificate on the bottom right below the expiry date.

New Recertification Programme from April 2013

From 1 April 2013, all practising pharmacists must be enrolled with the approved recertification programme ENHANCE 2.0, provided by the Pharmaceutical Society of New Zealand. The programme will be the same for members and non-members of the Society.

This programme was developed to meet the [new recertification framework](#) finalised by the Council last year. The programme is approved until March 2016, subject to the provider addressing key points raised by Council. This must be done before March 2014.

Approval of new recertification programme - Timeline

2010

- Pharmacy Council agrees on draft recertification framework for further development by a working party.
- Recertification working party established:
Members include a rural pharmacist, a recently-registered pharmacist, a lay member and representatives for Pharmacy Guild of New Zealand, Pharmaceutical Society of New Zealand, New Zealand College of Pharmacists and New Zealand Hospital Pharmacists Association, The working party was chaired by a Pharmacy Council Council member.

2011

- Working party finalises the framework
- Pharmacy Council consults with the profession and other stakeholders

2012

- Consultation feedback reviewed
- Modified framework approved by the Council
- Framework guidelines developed
- Council meets with groups who expressed interest in providing a programme
- Three applications considered

- Two programmes approved until 2016 subject to addressing points raised by Council by March 2014

2013

- The Pharmacy Guild withdraws its recertification programme
- New recertification requirements apply from April

Intern Pharmacists' Assessment: Consultation Outcome

The Pharmacy Council consulted on a proposal for new assessments for intern pharmacists in late 2012. 105 responses were received over a six weeks period. The majority of respondents were in favour of introducing a multiple-choice question exam and an OSCE assessment. The new assessments will be introduced in 2014.

A full report on the consultation is available [here](#).

(Link is http://www.pharmacycouncil.org.nz/cms_show_download.php?id=365)

CPSA – Your Professional Obligation

As anticipated, there has been considerable discussion about the implementation of the new Community Pharmacy Service Agreement (CPSA) and what is expected of pharmacists. Naturally, much of this has focussed on the new funding arrangements, but there has also been considerable “noise” about what the LTC etc. services actually mean from a patient management perspective. Regardless of whether the patient is a core patient or if they are enrolled into the LTC, LTC-EC, or PHARM ‘service’, and regardless of what you believe the expectations are for each of these services, we’d like to remind you of your ethical and professional obligations to the patient.

The Code of Ethics underscores the need to make the health and well-being of your patients your first priority, while the Competence Standards focus on all the relevant competencies needed to carry out the roles and services described in the pharmacist scope of practice.

In particular, Competence Standard 2 covers your role as a pharmacist *in promoting the quality use of medicines within an environment of professional pharmaceutical care. This includes selecting, recommending, monitoring and evaluating medicine therapy as part of a health care team.* Competence Standard 6 covers all aspects of dispensing including counselling each patient about the use of their medicine.

Elements in these two Competence Standards include assessing the effectiveness of the total medicine therapy. This covers the need to identify any changes to medicine therapy that may need to be considered, follow up on non-compliance and/or poor adherence issues and above all, effective communication with the patient and other health professionals.

So regardless of the CPSA ‘service’ a patient is eligible for, all patients should expect these services as a minimum from every community pharmacist.

Pharmacist Prescribers

In December 2012, Cabinet approved the drafting of the Pharmacist Prescriber regulations. These regulations will enable clinical pharmacists, who have successfully completed the new postgraduate certificate in pharmacist prescribing, to prescribe medicines to patients who are being cared for by a multi-disciplinary and collaborative healthcare team. The Pharmacist Prescriber will work with a designated medical practitioner who will act as a mentor and advisor to the team. Diagnosis and wider patient management will remain the responsibility of the medical practitioner.

The pharmacist prescriber role is seen as a natural extension of an experienced clinical pharmacist's role. Patients will still need to see a GP, they will not be able to consult a pharmacist directly to obtain a prescription and the pharmacist prescriber will not be able to dispense prescriptions they write.

Once finalised and approved by both the Cabinet Legislation Committee and Cabinet, the regulations and the new Pharmacist Prescriber Scope of Practice, will be notified in the *New Zealand Gazette*. Although we don't have an exact timeframe, it should be noted that the regulations will not come into force until at least 28 days after they have been notified.

PRACTICE ISSUES

Professional indemnity insurance – do I need it?

Obligation 7.3 under the Code of Ethics states that practising pharmacists MUST:

“Ensure that all professional activities that you undertake or are responsible for are covered by appropriate professional indemnity arrangements.”

The following case example from Pharmacy Defence Association (PDA) illustrates why professional indemnity insurance is essential and, more specifically, what serious consequences can occur if you don't have the right indemnity protection.

A hospital pharmacist, who was originally registered in another country and had been registered in New Zealand for 12 months, agreed to assist a community pharmacist by completing a locum on a Saturday morning. A hospital doctor, originally registered in the UK, prescribed trimethoprim 50mg bd for a UTI for a 4 year old child.

The hospital pharmacist could not find any trimethoprim 50mg on the shelf (because it is not available in NZ) or in the available reference sources. The technician offered to help her and, through a computer search which the hospital pharmacist was not familiar with, the technician borrowed **trimipramine (Tripress) 50mg** capsules from a nearby pharmacy.

After receiving the prescription, the mother sprinkled the capsule contents onto the child's food which the child then ate. The child became drowsy, could not be woken three hours later, was hospitalised at which time the error was discovered.

The Health and Disability Commissioner found both the technician and the dispensing pharmacist liable. The dispensing pharmacist's prosecution personally cost her thousands of dollars as her professional indemnity protection at the hospital, provided by the DHB, did not protect her in the community setting. If she had had professional indemnity insurance for her work in the community pharmacy, her legal costs would have been covered. The pharmacy and the pharmacy owner were found vicariously liable although the owner was not prosecuted.

This situation is a prime example where the lack of appropriate professional indemnity insurance had wide ranging ramifications.

Medicine Recalls

Following concerns expressed to Council recently that some pharmacists are *“refusing to co-operate with recalls unless they get paid to do so”*, it is timely to look at pharmacists obligations in this area.

In 2010, in response to concerns raised by the profession over the costs involved in patient-level medicine recalls, the Ministry of Health and a number of key pharmacy stakeholders reviewed the

Ministry's Recall Code. The subsequently revised code was never ratified but was put on hold while a number of court cases were resolved.

It is now the intention of the Pharmacy Guild to readdress these discussions with the Ministry and other interested parties to ensure the Recall Code satisfies all stakeholders. Currently, while pharmacists do have the right to be reimbursed appropriately for their time, there are a number of codes and standards, including the Code of Ethics, which regulate pharmacists obligations to respond appropriately.

Prescribing outside Scope of Practice

There have been questions raised again about non-medical prescribers prescribing outside their scope of practice – most recently, an orthodontist prescribing aqueous cream and emulsifying ointment for his/her son.

The Medicines Regulations (39) only allow an authorised prescriber to prescribe a prescription medicine if it is for the treatment of a patient under their care **and** if it is in accordance with their scope of practice. The Ministry of Health have previously stated that '**pharmacists should continue to dispense prescriptions on their face**' and accept that what is prescribed is legitimate, unless there is reason to believe that a prescription does not legally comply.

If you believe the prescription is outside the prescribers scope of practice or you have clinical concerns about the prescription or a prescriber, you should contact the relevant authority ie Dental, Nursing, Midwifery etc Council.

Health Practitioners Disciplinary Tribunal cases

1. Mismanagement and poor practices result in suspension and conditions on practice - Terry Osborne, Auckland

A professional conduct committee charge resulted in the Tribunal finding that Mr Osborne was guilty of professional misconduct having acted in breach of a multitude of legislative requirements, and the Pharmacy Council Code of Ethics.

A number of Ministry of Health audits had identified that Mr Osborne had not operated his pharmacies in accordance with legal requirements. These failures were wide-spread and over a significant period of time. They raised public health and safety risks, and highlighted that Mr Osborne lacked a working knowledge of the law and the skills to ensure competent practice. Mr Osborne had assured the Ministry that he had made changes when he had not. It was not until 2011, when the Ministry proposed to suspend his pharmacy licence that he sought help. At that stage the Council was informed of the matter.

The issues identified included:

- allowing unqualified persons to dispense medicines
- failing to lock up controlled drugs, to maintain a controlled drugs register, to conduct stock takes of controlled drugs, and to properly manage prescriptions for controlled drugs
- allowing controlled drugs to be stored in a private vehicle
- failing to develop and update standard operating procedures and ensure they were implemented at the pharmacies
- recycling medicines by re-packaging medicines that were in compliance packs
- failing to ensure medicines were properly labelled, with their batch and expiry dates

- generally failing to ensure that the pharmacies were managed and operated in a professional and competent manner.

Mr Osborne was censured, ordered to pay costs and a fine totalling \$35,000.00, suspended for three months, and had several conditions placed on his practice for a 12 month period after suspension. These conditions include passing the New Zealand Pharmacy Legislation course, entering into a mentoring relationship, and reporting requirements. When assessing the penalty the Tribunal took into account that Mr Osborne had engaged a pharmacy consultant to provide assistance and advice on the operation of his pharmacies and that his competence had been reviewed by the Pharmacy Council.

The full decision is available at: <http://www.hpdt.org.nz/portals/0/phar12214p%20decisionweb.pdf>

2. Failure to comply with legal requirements for Class C drugs results in cancellation of registration - Arief Katamat, Auckland

In September 2011 the Tribunal found Mr Katamat guilty of professional misconduct for:

- Failing to properly record the order and sale of Class C drugs and prescription-only medicines, including the failure to maintain a Controlled Drugs Register.
- Selling prescription-only medicines without a prescription.
- Failing to label medicines and keep proper records of their sale in a prescriptions register.
- Failing to ensure certain Class C drugs were properly stored.

The most serious findings were that Mr Katamat failed to keep adequate records of orders and sales of Sudomyl and codeine phosphate. Over 26,000 Sudomyl tablets and over 25,500 codeine tablets had been ordered by Mr Katamat's pharmacies and were unaccounted for in the pharmacies' records. Mr Katamat's defence was that he had been set up by his employees and that they had in fact ordered the drugs. He also suspected them of theft and harbouring animosity toward him. This was not accepted by the Tribunal.

The Tribunal cancelled Mr Katamat's registration, censured him, and ordered that he pay more than \$78,000 in costs.

Mr Katamat appealed the penalty to the High Court. The Court found his conduct was 'very serious' and upheld the Tribunal's decision to cancel his registration and censure him. It noted that the Sudomyl and codeine charges were particularly significant, as the drugs are very dangerous if not properly managed. The Court assessed the Tribunal's decision and found it to be consistent with penalties imposed in similar cases, and supported the Tribunal's view that the prospect of rehabilitation of Mr Katamat was low. The Court upheld the appeal against the costs awarded by the Tribunal on the basis that Mr Katamat is bankrupt.

The Council is extremely disappointed that costs are not able to be recovered as the cost to the profession for the case is in excess of \$280,000.00.

See also November 2011 Council Newsletter: 'Supply of unnecessary or excessive quantities of drugs'.

The full Tribunal decision is available at:

<http://www.hpdt.org.nz/portals/0/phar10162pdecisionsub.pdf>

The Tribunal penalty decision is available at:

<http://www.hpdt.org.nz/portals/0/phar10162pdecisionpenalty.pdf>

Has Your Address or Contact Details Changed?

If your address or contact details change, please remember to let us know.

Email enquiries@pharmacycouncil.org.nz or log in to your Pharmacy Council account.

How to Contact Us at the Council

Registration enquiries

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