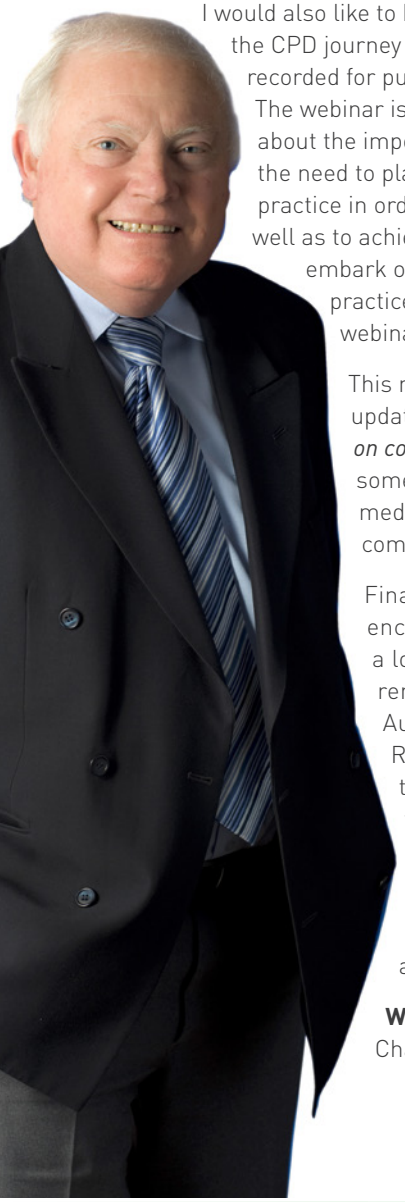
PHARMACY BOARD OF AUSTRALIA news
Issue 13 – October 2016
Pharmacy Board of Australia

Chair's message

Welcome to the latest edition of the Pharmacy Board of Australia's Newsletter. In this newsletter we will update you on a number of important practice issues and provide information on the upcoming registration renewal period.

We will also highlight the applications that pharmacy graduates must complete and have approved by the Board before they can start their internship. These include an application for provisional registration which can be submitted through the online graduate applications portal at www.ahpra.gov.au, and an application for approval of supervised practice.

To coincide with the September meeting of the Board which was held in Brisbane, the Board held a meet-and-greet event on Thursday 22 September 2016 at the Pullman Brisbane, where it welcomed 40 attendees from the greater metro Brisbane area. The event was a great opportunity for the Board to discuss pharmacy issues of relevance to students, local community and hospital-based pharmacists, and key pharmacy stakeholders.



I would also like to highlight the Board's webinar on the CPD journey held on 15 September, which was recorded for publishing on the Board's website. The webinar is a good reminder to pharmacists about the importance of lifelong learning and the need to plan CPD relevant to scope of practice in order to maintain competence, as well as to achieve competence if wanting to embark on new activities and scopes of practice. If you have not yet reviewed the webinar, I encourage you to take a look.

This newsletter also includes an update on the Board's *Guidelines on compounding of medicines* and some further discussion on when medicines should (and should not) be compounded by pharmacists.

Finally, I would like to remind and encourage pharmacists to keep a look out for the registration renewal reminder from the Australian Health Practitioner Regulation Agency (AHPRA), and to renew their registration on time by 30 November 2016.

Hopefully, you will find the newsletter interesting and its content relevant. Your feedback is always welcome.

William Kelly
Chair, Pharmacy Board of Australia

Contents

Continuing professional development requirements

The Board's revised *Registration standard: Continuing professional development* requires pharmacists to plan their CPD and complete CPD activities that are relevant to their scope of practice. This standard came into effect on 1 December 2015 and applies to the current registration period.

At renewal of registration, pharmacists will be expected to declare whether, during the preceding period of registration, they met the Board's CPD requirements as outlined in the standard, including:

- planning CPD relevant to their scope of practice, and
- completing CPD activities that have an aggregate value of 40 or more CPD credits for the 12 month period ending 30 September 2016.

A documented CPD plan will not need to be submitted at renewal of registration. However, if selected for audit of compliance with the CPD standard, a pharmacist would need to provide evidence of planning CPD relevant to their scope of practice as well as evidence of the associated CPD activities.

The Board notes that the pharmacy professional associations have developed educational activities for pharmacists on CPD, as well as additional support tools to help pharmacists in

meeting the Board's CPD requirements. The Board encourages pharmacists to contact the pharmacy professional associations about the support available.

To support pharmacists in understanding and meeting their CPD obligations, the Board also held a webinar on 15 September on 'The continuing professional development (CPD) journey'.

The webinar was presented by Northern Territory practitioner Board member Ms Bhavini Patel, and covered:

- The concept of lifelong learning – Why it is important to plan your CPD.
- The CPD cycle – Plan, Do, Record, Reflect, Incorporate into Practice.
- Different ways to learn.
- How reflective practice can accelerate your professional development.
- The Board's new CPD requirements.
- Available CPD resources and tools.

Participation in the webinar (or viewing the recording at a later date) may count as CPD (unaccredited) and contribute towards pharmacists meeting the Board's requirements.

A recording of the webinar has been published on the Board's website. It was great to see many participants take advantage of the Q&A session at the end of the webinar. A frequently asked questions document from the session has been published with the webinar recording.

Thank you to all participants who took part in the quick survey at the end of the webinar. Your feedback will help identify topics of interest about the regulation of pharmacists for future webinars.

Reminder to renew online, on time

Pharmacists with general or non-practising registration are due to renew online by 30 November 2016.

Under the National Law[1], registered health practitioners are responsible for renewing their registration on time each year.

A series of new-look reminders to renew online are being sent to practitioners by AHPRA on behalf of the Board. The email reminders include a helpful information box with links to the password reset function and to a video explaining how to renew online.

Further information

Useful information for pharmacists is on the Board's website:

- Registration standards
- Registration renewal
- Renewal FAQ

Registration fees for 2016/17

Last month the Board announced that the general registration fee has been set at $328, limiting the increase to indexation. It applies from 1 September 2016 and covers the registration period for most pharmacists of 1 December 2016 to 30 November 2017.

The fee for general registration for pharmacists whose principal place of practice is NSW[2] is also $328. A fee schedule is published on the Board's website. The National Scheme[3] is funded by practitioners' registration fees and there is no cross-subsidisation between professions.

More detailed information about the Board's financial operations will be outlined in the health profession agreement between the Board and AHPRA for 2016/17, which will be published on the website soon. This agreement sets out the partnership between the Board and AHPRA, and the services AHPRA will provide to support the Board to regulate pharmacists.

Revised registration standards in effect

Professional indemnity insurance

Pharmacists are reminded they must meet the revised registration standard for professional indemnity insurance (PII) arrangements by 30 November 2016.

In effect since 1 July 2016, the new standard continues to set a minimum amount of cover of $20 million which reflects the industry standard.

There have been some minor changes to the PII requirements, with the new standard specifically requiring policies to have retroactive cover and automatic reinstatement. There is also additional detail in relation to:

- third party cover and run-off cover
- the need to conduct a self-assessment and seek expert advice on whether more than the minimum amount of cover is required
- the need to notify the Board within seven days if PII arrangements are no longer in place
- the required evidence of the PII arrangements in place, and
- consequences if a pharmacist does not meet the standard.

The Board encourages all pharmacists to review the new registration standard to check whether their current PII arrangements will need to be adjusted to meet the requirements of the new standard.

If your PII arrangements do not meet the requirements of the standard, you will need to contact your insurer, and if necessary, have your policy adjusted so that it meets the new standard by the time you renew your registration.

1 The Health Practitioner Regulation National Law, as in force in each state and territory (the National Law).

2 NSW is a co-regulatory jurisdiction.

3 The National Registration and Accreditation Scheme.

More information about the new PII arrangements standard, including the brief consultation report, FAQ and a fact sheet, is available on the Professional indemnity insurance arrangements page of the AHPRA website.

Other revised standards

With renewal of registration due 30 November 2016, pharmacists are reminded of the Boards' new standards for:

- continuing professional development (CPD), and
- recency of practice.

These came into effect on 1 December 2015, as well as new guidelines on CPD, and therefore apply to the upcoming cycle of renewals.

Pharmacists should review the new registration standards to ensure they meet the requirements before they renew.

Advertising obligations

The Pharmacy Board has published further information for pharmacists to help practitioners to better understand their advertising obligations.

Section 133 of the National Law regulates the advertising of regulated health services (a service provided by, or usually provided by, a health practitioner as defined in the National Law).

Section 133 provides that a person must not advertise regulated health services in a way that:

a) is false, misleading or deceptive or is likely to be misleading or deceptive; or

b) offers a gift, discount or other inducement to attract a person to use the service or the business, unless the advertisement also states the terms and conditions of the offer; or

c) uses testimonials or purported testimonials about the service or business; or

d) creates an unreasonable expectation of beneficial treatment; or

e) directly or indirectly encourages the indiscriminate or unnecessary use of regulated health services.

For the latest information published by the Board on advertising obligations please refer to Further information on advertising therapeutic claims. This information does not replace the Board's Guidelines for advertising regulated health services, which should be your first point of reference to understand your obligations. You may also wish to seek appropriate advice, for example, from your legal advisor and/or professional association.

The burden is on you to substantiate any claim you make that your treatments benefit patients. If you do not understand whether the claims you have made can be substantiated based on acceptable evidence, then remove them from your advertising.

AHPRA is responsible for prosecuting breaches of the advertising requirements in the National Law. This means that AHPRA with National Boards needs to decide whether there has been a breach of your advertising obligations.

As part of this process, we will use objective criteria to assess whether there is acceptable evidence to substantiate therapeutic claims in advertising. We will use appropriate experts to help us evaluate evidence where needed.

These are serious matters that can have serious consequences for your professional standing and your criminal record: **if in doubt about a claim, leave it out of your advertising**.

Advertising obligations and other relevant legislation

If your advertising involves the advertising of products and/or therapeutic goods you must take care that you comply with all relevant legislation. Australian regulators such as the Australian Competition and Consumer Commission (ACCC) and the Therapeutic Goods Administration (TGA) have a responsibility for laws governing the advertising of health products and services. More information about this is included in the Board's Guidelines for advertising regulated health services.

If a complaint about an advertisement may be of interest to another Australian regulatory authority such as the TGA or ACCC, AHPRA may refer the matter to the most appropriate regulator.

Online graduate applications for provisional registration now open

AHPRA is now calling for final-year pharmacy students to apply for registration online.

An email to pharmacy students on the Student Register urges individuals who will complete their approved program of study by the end of 2016 to apply online for provisional registration four to six weeks **before** finishing their course.

Certain applicants will also need to apply for an international criminal history check.

All applicants need to post hardcopies of supporting documents to AHPRA to complete their application. Information about the supporting documents is included in the *Next steps checklist* which is emailed to each student upon receipt of their online application.

Students are encouraged to read the information on AHPRA's website under Graduate applications. The Board's video for graduates explains what they need to do to be granted provisional registration and what they need to know to stay registered, including the ongoing obligations of a registered pharmacist.

Once provisional registration is obtained, a registrant (intern) must meet the Board's registration standards. The *Registration standard: Supervised practice arrangements* also outlines that interns must have their supervised practice approved before they start practising. Interns can start supervised practice as soon as their name is published on the national register of practitioners.

Internships and approval of supervised practice

By now, most final-year pharmacy students will have secured an internship to complete the 1824 hours of supervised practice and an intern training program which are required for general registration. The Board would like to remind pharmacists that there may be some students who haven't yet secured a supervised practice site and encourages pharmacists to consider becoming a preceptor.

The role of preceptor is an important one and the Board expresses its appreciation of the efforts of pharmacists in training our future pharmacists. The benefits of being a preceptor include:

- supporting the profession – the future of pharmacy
- diversifying skills
- strengthening pharmacy practice
- maintaining knowledge, and
- the potential for future recruitment of a newly-qualified pharmacist.

New and current preceptors should consider undertaking preceptor training as part of CPD relevant to their scope of practice, and are encouraged to make enquiries with CPD providers about available courses.

Meeting your obligations

Information about supervised practice is outlined in the *Registration standard: Supervised practice arrangements*, as well as the *Intern pharmacist and preceptor guide* available on the Internships page of the Board's website. Preceptors need to be willing to commit themselves to fulfilling the role requirements set out in the guide as part of their professional responsibilities and duty of care to the intern pharmacists they supervise.

The Board has previously warned that interns who do not gain provisional registration and the Board's approval of their supervised practice hours before starting their supervised practice would breach the standard. This puts interns at risk of not meeting the requirements for general registration and may affect their eligibility to gain entry to the written and oral examinations.

The Board reminds final-year students and prospective preceptors that they must meet their obligations regarding registration and supervised practice as highlighted in the preceding newsletter article.

Compounding guidelines update

The Board is currently having further discussion with the TGA about draft revisions to the currently postponed section *Expiry of compounded parenteral medicines* of the Board's *Guidelines on compounding of medicines* (the guidelines). Feedback received through the February-March 2016 public consultation has enabled the Board to identify several outstanding issues requiring further discussion with the TGA, after which submissions will be published on the Board's website unless an individual or organisation has requested otherwise.

Further updates will be provided by the Board when available, including when revised guidance will be finalised and take effect.

When should a medicine be compounded?

The guidelines outline that a compounded medicine should be provided if the medicine is safe and appropriate for the patient.

Pharmacists need to be prudent when determining if it is appropriate to compound a medicine, regardless of whether the medicine has been prescribed or is being supplied over the counter, and follow the overarching guidance in the guidelines. This guidance states that compounding should only take place where:

- an appropriate commercial product is unavailable
- a commercial product is unsuitable (e.g. if a patient experienced an allergy to an excipient in the commercial product), or
- when undertaking research sanctioned by a recognised human research ethics committee.

The guidance also states that if the medicine to be compounded would be a close formulation to an available and suitable commercial product, and would not be likely to produce a different therapeutic outcome to the commercial product, then the compounding should not take place.

Commercial products that are on the Australian Register of Therapeutic Goods have been evaluated by the TGA for quality, safety and efficacy.

When compounding medicines, pharmacists must ensure that there is good clinical and pharmaceutical evidence to support the quality, stability (including appropriate expiry periods), safety, efficacy and rationality of any extemporaneous formulation. This may involve collaboration with the prescriber, so an agreement on the suitability of the product for the intended patient is able to be achieved.

The compounding of medicines by pharmacists may benefit certain patients whose medical needs are unable to be met by a commercially available product. For example if a patient has an allergy to a preservative contained in the commercially available product, or if a lower strength of a commercially available product is required, for example for a child, elderly patient or animal.

When compounding a medicine for a patient, the information provided about the medicine should include an explanation of why a compounded product is being supplied, and how this differs to a commercially-available medicine which requires the manufacturer to meet the requirements of the TGA for addition of medicines to the Australian Register of Therapeutic Goods.

Pharmacists who compound any medicine must be mindful of the associated risks, and are reminded that all compounding should be carried out in accordance with relevant legislation, practice standards and guidelines, including the Board's guidelines.

Practice advice

Applying the Board's code of conduct and guidelines in practice

There may be circumstances in practice where pharmacists are required to apply the Board's Code of conduct for pharmacists, as well a range of the Board's guidelines, to ensure the matter is dealt with appropriately in order to minimise risk and obtain good health outcomes for patients.

The principles contained in the Board's code of conduct should underpin the day-to-day practice of a pharmacist. It provides a framework to guide a pharmacist's professional judgement, and addresses some of the broader obligations of pharmacists to their patients such as the provision of patient-centred care, communicating effectively, and collaborating with other health practitioners who have care of the patient in order to enhance patient care.

The Board's guidelines may link to more specific issues encountered by pharmacists. For example, the *Guidelines on practice-specific issues* address specific services provided by pharmacists with particular reference to drugs of dependence. The *Guidelines on dose administration aids and staged supply of dispensed medicines* highlight additional considerations for pharmacists who supply dose administration aids to patients. They also address the periodic supply of medicines to patients, often drugs of dependence, in order to protect vulnerable patients from the potential harm to such medicines. Further, the *Guidelines for proprietor pharmacists* address a range of additional obligations of proprietor pharmacists including the need to ensure that pharmacies are suitably resourced to enable the safe provision of pharmacy services to the public.

At times, pharmacists may be presented with circumstances that are not routine, and maintaining an awareness of the range of issues addressed in the Board's guidelines can help pharmacists in appropriately managing such circumstances. Consideration should also be given to the practice standards published by the profession, as well as the requirements outlined in relevant state, territory and Commonwealth legislation.

With the revision and publication of revised guidelines by the Board which came into effect on 7 December 2015, pharmacists are encouraged to review these documents periodically, and ensure they are across the changes, some of which were highlighted by the Board in its 2 September 2015 news item. Pharmacists should also reflect on their own practice, and whether any changes can be implemented to ensure their practice reflects their legal and professional obligations and supports safe outcomes for patients.

Bulk sale of scheduled medicines

Under the National Law, New South Wales (NSW) is a co-regulatory jurisdiction, with the Pharmacy Council of New South Wales (the Council) working with the Health Care Complaints Commission in managing concerns about pharmacists' conduct, health and performance in NSW.

A recent Council newsletter included an item about the bulk sale of scheduled medicines which has relevance to pharmacists in all jurisdictions and the following details are provided with the Council's permission.

The Council has noticed a recent increase in reports of pharmacies participating in bulk selling of goods, akin to wholesaling, with bulk purchase requests involving in some instances over 100 packs of a medicine in a single purchase.

This raises issues such as contravention of jurisdictional drugs and poisons legislation, noncompliance with practice standards and Board guidelines, and practice not aligning with the National Medicines Policy. The policy aims to ensure the quality use of medicines, stating that *'medicines, whether prescribed, recommended, and/or self-selected should be used only when appropriate…'.*

Pharmacists, as partners to the policy, must use their knowledge and skill to make informed recommendations to patients and to counsel on how to use medications for optimal outcomes. If asked to sell scheduled medications in bulk, pharmacists are unable to determine the appropriateness of what is being requested relative to the patient who takes the medication.

This matter is also addressed in the Board's *Guidelines on practice-specific issues*, which state in Guideline 4 *Supply of Schedule 2 poisons (Pharmacy Medicines) and Schedule 3 (Pharmacist Only Medicines)* that only one proprietary pack of Pharmacy Medicines and Pharmacist Only Medicines is to be supplied at a time, unless there are exceptional circumstances clearly demonstrable by the customer, additional documentation of which should be kept.

The Council has also noted recent social media forums circulating photos of a souvenir store selling scheduled medicines, which raises the issue of how these medicines were obtained, which may be through the bulk supply from pharmacies.

Pharmacists are reminded of their obligations to supply appropriate quantities of scheduled medicines.

Expired medication

The Board would also like to highlight to pharmacists that it has recently seen a small number of notifications which relate to the dispensing of expired medication. The Board reminds pharmacists of one of their basic obligations when dispensing medicines – to ensure that the expiry date of a dispensed medicine is valid for the expected duration of treatment. Suitable processes should be in place in the pharmacy to support this, including routine checks of dispensary stock expiry dates, as well as checking the expiry date of a product at the point of dispensing.

Notifications case study – Dispensing procedures and proprietor responsibilities

The allegation

A notifier alleged that a patient was issued a repeat authorisation by a pharmacy for two additional supplies of a prescribed medicine without the authority or direction of the prescriber. A further two repeat supplies were subsequently dispensed in error. The original prescription clearly directed no repeats.

The issues

The allegation raised questions about the dispensing processes within the pharmacy, and how the initial error, made by a dispensing technician in training, was not picked up by the pharmacist before the medicine and repeat authorisation were supplied to the patient.

The allegation also raised the issue of recording initials and signatures during the dispensing process. In this case, the dispensing technician had entered their own initials in the system as the dispenser, and despite the process at the pharmacy being that the checking pharmacist initials the dispensing label, this did not take place on any of the three occasions that the medicine was dispensed. Therefore, the pharmacist(s) responsible for the dispensed medicine could not be identified from the available records.

The allegation raised issues concerning proprietor responsibilities as outlined in the Board's *Guidelines for proprietor pharmacists*, which includes ensuring that a pharmacy is suitably resourced and that staff members are suitably trained and appropriately supervised, that appropriate risk management procedures are in place for the operation of the pharmacy, and that business procedures, policies and protocols are routinely followed.

The outcome

The proprietor advised that since the incident occurred, steps and processes at the pharmacy have changed to ensure medication is appropriately dispensed and proper checks and balances are in place. Staff education is now also occurring on a weekly basis, and changes to dispensing processes allow pharmacists to spend more time with customers and reviewing dispensed medicines before they are handed out to the patient.

The proprietor was cautioned. An audit is also to be carried out after three months to ensure the changes advised by the proprietor have been implemented and are routinely followed to ensure public safety.

Lessons to be learnt

The notification highlights the importance of proprietors being aware of and fulfilling their professional obligations and responsibilities in ensuring that their pharmacy business is conducted in an appropriate manner.

It also highlights the importance of pharmacists accepting responsibility for dispensed medicines by making appropriate records (by placing initials or signatures) in the prescription records of the pharmacy and any other place according to the relevant legislation (refer to *Guideline 1 – The dispensing process* of the Board's *Guidelines for dispensing of medicines*). This applies in all practice settings.

The Board has not prescribed how this should occur. However, pharmacists need to ensure they meet their obligations by recording responsibility during the process of dispensing. In order to be held accountable for their own dispensing practice only, pharmacists need to ensure that robust procedures are implemented and followed to avoid any confusion when working with other pharmacists and/or supervising dispensary assistants/technicians.

For this reason it is important that pharmacists protect their initials in the dispensing software, for example, by using passwords when accessing the dispensing program, logging out of the dispensing program and avoiding the use of initials used by their colleagues.

Tribunal decision

A pharmacist convicted of drug trafficking has been disqualified by a tribunal from applying for registration for three years.

The Victorian Civil and Administrative Tribunal (the tribunal) found in July 2016 that Ali Kozanoglu had engaged in professional misconduct and disqualified him from applying for registration as a registered pharmacist for three years from 3 August 2016. He was also reprimanded by the tribunal

In March 2015, Mr Kozanoglu was convicted in the County Court of Victoria of two counts of trafficking a drug of dependence, namely dextromethorphan, between 1 June 2010 and 23 June 2011. He was convicted and sentenced to three years' imprisonment. All but nine months of the jail term was suspended on the basis that Mr Kozanoglu be of good behaviour for three years.

The Pharmacy Board of Australia (the Board) referred allegations concerning Mr Kozanoglu to the tribunal in February 2016. The Board alleged that he had engaged in professional misconduct by trafficking a drug of dependence and subsequently receiving criminal convictions for this conduct.

The Board also refused Mr Kozanoglu's application for renewal of general registration as a pharmacist. In May 2016, Mr Kozanoglu filed an application with the tribunal for review of the Board's decision. However, he abandoned that application for review a month later.

The tribunal found that Mr Kozanoglu had engaged in professional misconduct on the basis that his conduct leading to his convictions, and the convictions in themselves, amounted to conduct substantially below the standard reasonably expected of a registered health practitioner of an equivalent level of training or experience.

In making that finding, the tribunal observed that, *'to say (Kozanoglu's) conduct, as found by a jury, leading to conviction, was substantially below the expected standard is an understatement'.*

The tribunal went on to state that:

'The fundamental obligation of a pharmacist is to ensure the health and wellbeing of their patient(s). This is achieved by providing appropriate high-quality treatment including appropriate provision of medicine(s), as well as safeguarding people from inappropriate treatment and medication use. Mr Kozanoglu betrayed that obligation.'

In imposing the three-year disqualification period, the tribunal noted that a substantial disqualification period was required in order to 'send a message of deterrence to pharmacists and to uphold the profession's reputation'.

The tribunal also affirmed the Board's decision to refuse Mr Kozanoglu's application for renewal of his registration noting the application for review had been abandoned.

The reasons for the tribunal's decision will be published on the AustLII website.

Other state and territory court and tribunal decisions are available on AHPRA's website.

Keep in touch with the Board

- Visit www.pharmacyboard.gov.au for the mandatory registration standards, codes, guidelines and FAQ. Visiting the website regularly is the best way to stay in touch with news and updates from the Board.
- Lodge an online enquiry form.
- For registration enquiries, call 1300 419 495 (from within Australia) or +61 3 9275 9009 (for overseas callers).
- To update your contact details for important registration renewal emails and other Board updates, go to the AHPRA website: Update contact details.
- Address mail correspondence to: William Kelly, Chair, Pharmacy Board of Australia, GPO Box 9958, Melbourne, VIC 3001.

Pharmacy Board of Australia