PHARMACY BOARD OF AUSTRALIA news
Issue 8 – March 2015
Pharmacy Board of Australia

Contents

New guidance on compounding of medicines

The Board has released new guidelines and other tools for registered pharmacists who compound medicines.

Pharmacists who regularly compound medicines are urged to read the:

- *Guidelines on compounding of medicines*
- *Background on the regulation of compounding by pharmacists, and*
- *Professional practice profile for pharmacists undertaking complex compounding.*

The *Guidelines on compounding of medicines* were subject to wide-ranging consultation and will take effect on 28 April 2015.

The guidelines have been published now so pharmacists can become familiar with their content before implementation.

They replace *Guideline 5 Extemporaneous dispensing (compounding)* from the Board's *Guidelines for dispensing of medicines* published on 12 August 2010.

The *Background on the regulation of compounding by pharmacists* contains information on the requirements of other authorities under their specific legislation, which relate to compounding. Each jurisdiction has separate requirements which may be specified in legislation and guidelines for these purposes.

The *Professional practice profile for pharmacists undertaking complex compounding* outlines the required competencies of pharmacists undertaking complex compounding. It can assist pharmacists to acquire and maintain the required competence for any type of complex compounding and can also be used by course providers to develop training programs.

The circumstances under which pharmacists may compound and supply extemporaneously prepared medicines in and from different types of premises, or require a manufacturing licence from the Therapeutic Goods Administration (TGA), can be accessed on the Therapeutic Goods Administration website.

The TGA is in the final stages of consultation about possible changes to the regulation of compounded medicines. When the TGA publishes its revised legal framework, the Board will revisit its guidelines to ensure that these are aligned with any new requirements and continue to provide protection of the public.

The compounding guidelines and supporting tools are available on the Codes and guidelines page of our website.

Public consultation on guidelines closes 1 May 2015

The Board is currently consulting on the following revised guidelines:

- *Guidelines for dispensing of medicines*
- *Guidelines on practice-specific issues*
- *Guidelines on dose administration aids and staged supply of dispensed medicines*[1]*, and*
- *Guidelines for proprietor pharmacists*[2]

The consultation paper is published under Current consultations on our website.

Consultation will close on 1 May 2015 and the community, stakeholders, pharmacists and other health practitioners are welcome to make a submission.

Stephen Marty
Chair, Pharmacy Board of Australia

1 Currently titled *Guidelines on specialised supply arrangement*
2 Currently titled *Guidelines on responsibilities of pharmacists when practising as proprietors*

Quarterly registration data

The Board publishes quarterly data profiling Australia's pharmacy workforce.

At December 2014, there were a total of 28,883 registered pharmacists comprising the following number of registrants according to registration type:

- 26,096 – general registration
- 1,724 – provisional registration
- 16 – limited registration, and
- 1,047 – non-practising registration.

The quarterly registration data at December 2014 for the pharmacy profession are published on the Board's website under About>Statistics. The report includes a number of statistical breakdowns.

Practice advice

Notifications case studies

The Notifications Committee of the Pharmacy Board of Australia (the NC) provides these de-identified case studies to the pharmacy profession in the expectation that, in future, such errors will be avoided.

Case 1 – Communication with the prescriber

The allegation

A notifier alleged that a pharmacist dispensed:

a. lamotrigine 25mg to a patient when topiramate 25mg was prescribed, and

b. hydromorphone HCl 4mg modified release (Jurnista®) to a patient when hydromorphone HCl 4mg (Dilaudid®) was prescribed.

The issues

The first allegation raised issues concerning dispensing errors, which have been addressed in previous newsletters including a failure to conduct a final check.

The second allegation raised the issue of whether a pharmacist must contact the prescriber and obtain approval to change the prescribed medicine.

In this case the pharmacist maintained that the prescribed medicine was not available and that an attempt to contact the prescriber was unsuccessful.

The outcome

The pharmacist was cautioned and conditions were imposed requiring the pharmacist to attend an education course relevant to dispensing medicines.

Lessons to be learnt

The pharmacist must always contact the prescriber and obtain the prescriber's authority to change medicines before any supply occurs.

This must be done notwithstanding that the prescribed medicine may not be available and the non-prescribed medicine is supplied on a short-term basis.

Case 2 – Dispensing from repeat authorisation

The allegation

A notifier alleged that a pharmacist incorrectly dispensed methylphenidate HCl 30mg (Ritalin LA®) to a patient with a label showing methylphenidate HCl 40mg (Ritalin LA®), which was in fact the medicine prescribed.

The issues

The allegations again raised questions concerning dispensing errors that have been identified in previous case studies.

The notifier also alleged that a pharmacist at a second pharmacy had subsequently incorrectly dispensed methylphenidate HCl 30mg (Ritalin LA®) to the patient, thus repeating the error made by the initial pharmacist.

The Board believed that the pharmacist at the second pharmacy dispensed the medicine from the repeat authorisation form without checking the original prescription.

In this case the patient suffered harm as a result of being supplied with incorrect medication.

The outcome

The pharmacist was cautioned.

Lessons to be learnt

The notification highlights the importance of checking medicines against the original prescription before the medicine is supplied to the patient.

Dispensing from a repeat authorisation form perpetuates any errors previously made during dispensing and places a patient at risk of harmful consequences.

Tribunal decisions

Mr Brian McAllan

The Queensland Civil and Administrative Tribunal has reprimanded pharmacist Mr Brian McAllan and found he had engaged in unprofessional conduct.

The matter dates back to March 2012 when AHPRA received a notification from the Drugs of Dependence Unit, Queensland Health, advising that Queensland Health had suspended Mr McAllan's endorsement to deal with schedule 4 drugs and schedule 2 and 3 poisons containing pseudoephedrine (PSE) for six months.

In November 2012, the Immediate Action Committee of the Pharmacy Board of Australia took immediate action and imposed conditions on Mr McAllan's registration, requiring him

to undergo six months of mentoring. These conditions were lifted in November 2013 because he had complied with them.

The Board has the power to take immediate action as an interim step to manage serious risk to the health and safety of the public, pending other inquiries.

After an investigation, the Board referred Mr McAllan to the tribunal. In its submission, the Board alleged that Mr McAllan had engaged in professional misconduct or unprofessional conduct under the National Law, and had breached the *Health (Drugs and Poisons) Regulation 1996 (Qld)* by:

- dispensing PSE in breach of the pharmacy's quality standard and
- dispensing PSE without satisfying himself of a genuine therapeutic need, and
- failing to record sales of PSE.

The Board also started separate disciplinary proceedings against Antonio Ciriello, the owner of the pharmacy where Mr McAllan worked, and pharmacist Robert Louis, who worked at the pharmacy.

Mr McAllan conceded that the Board had proven the allegations, and admitted that his conduct amounted to unprofessional conduct under the National Law.

The tribunal found that Mr McAllan had engaged in unprofessional conduct. It reprimanded him and ordered him to pay the Board's costs. The tribunal noted that it would have considered imposing conditions on Mr McAllan's registration, had he not already been subject to conditions by way of the immediate action process.

National Scheme news

New approach to international criminal history checks

As of 4 February 2015, National Boards and the Australian Health Practitioner Regulation Agency (AHPRA) have implemented a new procedure for checking international criminal history to provide greater public protection. This new approach requires certain applicants and practitioners to apply for an international criminal history check from an AHPRA-approved supplier. This approach aligns our international criminal history checks (ICHC) with our domestic history checks and aims to be fair and reasonable for practitioners. It also provides the Australian community with greater assurance by implementing additional safeguards to manage risks to the public from someone's international criminal history.

This approach was first announced in November last year, giving prospective applicants three months' notice of the change, and time to understand the new requirements before they take effect.

The new process for checking international criminal history aims to strike a balance between public safety and regulatory burden for practitioners.

For more information, please read the media release on the Board's website.

Boards and AHPRA strengthen national drug screening

Mandatory hair testing will be routine for all registered health practitioners with substance-related impairment, under a screening protocol to be introduced by AHPRA and the National Boards.

Under the protocol, all health practitioners who have restrictions on their registration linked to past substance abuse will have routine hair testing in addition to urine testing.

Routine hair testing helps provide comprehensive information about the use – over time – of a wide range of drugs (not just based on the practitioner's drug-taking history).

The protocol provides a clear framework across professions for AHPRA's advice to National Boards about the management of registered practitioners with drug-related impairment. It will make sure drug screening in the National Scheme is evidence based, effective and up to date.

National Boards will continue to make decisions about individual practitioners with impairment case by case, based on testing standards set out in the protocol. This includes:

- nationally consistent threshold limits, so all pathology providers conducting the tests use consistent testing baselines (e.g. will report all positive alcohol readings over 30pg/mg in hair)
- agreed 'critical events' – in addition to positive test results – requiring action and follow-up (e.g. unexplained delayed screening tests or results, failure to attend screening, diluted or unsuitable samples, etc.), and
- agreed triggers for National Boards to consider disciplinary action (e.g. positive test results, non-compliance with screening requirements, etc.).

AHPRA has established an expert panel to provide ongoing advice on the biological assessment, testing and monitoring of applicants and registrants with drug and/or alcohol misuse, including impairment. The panel includes Professor Olaf Drummer, Professor Jenny Martin and Dr Robert Ali. Terms of reference for the panel are published on the Expert Panel on Drug and Alcohol Screening page.

AHPRA is now seeking expressions of interest from pathology providers to provide drug screening services to AHPRA to support ongoing monitoring of practitioners known to have drug-related impairment.

The drug screening protocol is part of a wider, national strategy to effectively manage compliance and monitoring across the National Scheme. The strategy, progressively implemented from July 2014:

- applies to AHPRA's management, on behalf of National Boards, of all registered health practitioners with limitations on their registration related to health, conduct, performance or registration
- includes structural change, with the appointment of a national director, compliance and monitoring, and
- ensures coordination across all states and territories of AHPRA's compliance and monitoring program.

Background

AHPRA introduced an interim drug screening protocol nationally in July 2014 to guide the monitoring of practitioners with drug-related impairment.

The interim protocol was reviewed by independent expert Professor Olaf Drummer from Victorian Institute of Forensic Medicine, to ensure the approach to biological testing in the National Scheme was evidence based and up to date. His report is published on the Monitoring and compliance page.

AHPRA has updated the interim protocol in response to Professor Drummer's findings, including making it more specific about the drugs to be tested, the cut off levels for testing and introducing the use of hair testing. It will be further refined, fully implemented and published when AHPRA has selected an ongoing provider of pathology testing services. The proposed new protocol is published on the Monitoring and compliance page.

Security tip – keep your web browser updated

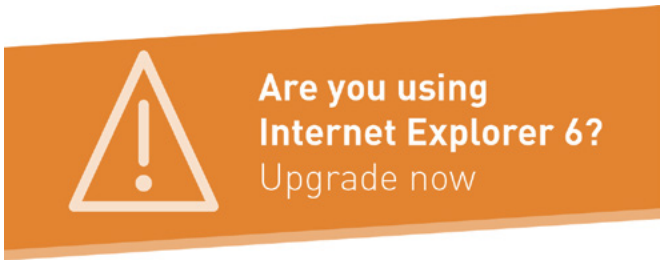
We are making changes to our websites to make sure that your information is kept safe.

From early April 2015, anyone using Internet Explorer version 6 (or an older version) to view our website is likely to experience difficulty accessing our web pages and our online services.

To avoid an interruption to service, we recommend you upgrade to the newest version of Internet Explorer immediately. It is available for free from Microsoft.

If you are using a new version of Internet Explorer and are still having difficulty accessing our site please contact us to report your experience:

- Call **1300 419 495** Monday to Friday, 9:00am – 5:00pm (Australian Eastern Standard Time).



For more information

- Visit the Board's website 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 enquiry form via the website by following the Enquiries link on every web page under *Contact us*.
- For registration enquiries, call 1300 419 495 (from within Australia) or +61 3 8708 9001 (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: Stephen Marty, Chair, Pharmacy Board of Australia, GPO Box 9958, Melbourne, VIC 3001.