PHARMACY BOARD OF AUSTRALIA news
Issue 11 – March 2016
Pharmacy Board of Australia

Contents

Chair's message

Welcome to the first newsletter for 2016 from the Pharmacy Board of Australia (the Board). This edition of the newsletter will update you on a number of important practice matters as well as more general Board information and National Scheme[1] news.

You may recall from the previous newsletter and publicity in the pharmacy press that in 2015 the Board consulted on and reviewed a number of registration standards and associated guidelines. One of these was the Board's CPD registration standard and guidelines. One of the changes in this CPD guidance was the introduction of a requirement that all pharmacists develop a CPD plan to assist in identifying areas in need of further development. This has been supported by additional information provided by way of FAQ including a sample plan template.

There is no compulsion to use the Board's template and the various pharmacy professional organisations offer support and plans to assist you.

CPD is more than just achieving the required number of credits each year, it is about identifying and undertaking your professional development in a more structured way and engendering a lifelong learning commitment.

Additional information on the CPD plan is provided in the newsletter or by accessing the CPD guidelines on the Board's website.

William Kelly
Chair, Pharmacy Board of Australia

1 The National Registration and Accreditation Scheme.

Public consultation on review of guidance on expiry of compounded parenteral medicines

In its December 2015 newsletter the Board advised that the *Guidelines on compounding of medicines* were in effect, with the exception of the section titled 'Expiry of compounded parenteral medicines'. The Board is now inviting interested parties to give feedback on draft revisions to the guidance in that section.

The consultation paper was released on 1 February 2016 and the consultation closes on **30 March 2016.**

You can access the public consultation paper and response template on the Current consultations page of Board's website.

We welcome your feedback.

Pharmacy regulation – recent tribunal decision

AHPRA on behalf of the 14 National Boards publishes a record of panel decisions and court and tribunal decisions about registered health practitioners. Summaries are published when there is clinical and educational value.

Pharmacy Board of Australia v Louis

The Queensland Civil and Administrative Tribunal (QCAT) has reprimanded a former pharmacist and found he engaged in unprofessional conduct for inappropriately dispensing pseudoephedrine (PSE), a drug which is well known to pharmacists for its potential for misuse and abuse.

The Pharmacy Board of Australia (Board) referred Mr Robert Donald Louis, a formerly registered pharmacist, to QCAT

regarding concerns about his practice between March 2009 and May 2011, when he worked part-time at the Nerang Day and Night Pharmacy.

The Board alleged that Mr Louis had engaged in professional misconduct by selling PSE:

- in breach of section 273A of the *Health (Drugs and Poisons) Regulation 1996* (Regulation), which means that when a pharmacy adopts a quality standard, a pharmacist must not sell a Schedule 2 or 3 poison unless the sale complies with the quality standard. PSE is a Schedule 3, Pharmacist Only, poison. Its potential for misuse and abuse is well known to pharmacists. The pharmacy adopted a quality standard and Mr Louis did not comply with the standard
- in breach of section 285A of the Regulation, which means that a person who sells PSE must, at the time of making the sale, record particulars for the sale as an electronic record that is accessible online by both the Chief Executive, Queensland Health, and the Commissioner of Police, and
- in the absence of a therapeutic need in breach of section 277 of the Regulation and contrary to the terms of his endorsements under section 257 of the Regulation. A pharmacist must not sell PSE unless they are reasonably satisfied that the purchaser has a therapeutic need.

In May 2011 Queensland Health had audited and analysed the pharmacy's dispensing data about PSE products. In December 2011, Queensland Health suspended for 12 months Mr Louis' endorsement for all drugs and poisons with PSE as the active ingredient and advised AHPRA.

In November 2012, the Board imposed conditions on Mr Louis' registration, all of which he complied with except for completing an oral legislation assessment. In December 2013, Mr Louis surrendered his pharmacy registration, having retired from practice.

Mr Louis conceded that the Board had proven the allegations and the parties jointly proposed a sanction which was accepted by the tribunal. QCAT found that Mr Louis had engaged in unprofessional conduct, reprimanded him and ordered him to pay the Board's legal costs.

- The QCAT decision is published on Austlii.

Registration renewal update

In the recent renewal period, 96% of pharmacy registrants renewed their registration and 98.7% of these did so online. This high rate of online renewal reflects the trend for all renewing practitioners across the National Scheme.

The Board will publish its next quarterly registration data update soon. For previous updates on the registered workforce, visit the Statistics page on the Board's website.

Australian Pharmacy Professional Conference and Trade Exhibition 2016

The Board participated in the Australian Pharmacy Professional Conference and Trade Exhibition 2016 (APP2016) on 18-20 March 2016. Board members and the Board's Executive Officer spoke with attendees at the Pharmacy Board of Australia stand and answered questions about pharmacists' obligations and the Board's role in the National Scheme.

A common topic of discussion was the development of a CPD plan and the Board's CPD documents and resources, which are published on the Board's website.

Board Chair William Kelly conversing with an APP2016 delegate

Practice advice

Biosimilar medicines

The use of biosimilar medicines is an emerging area of pharmacy practice. The Therapeutic Goods Administration (TGA) provides the following definition on its website:

A biosimilar medicine is a version of an already registered biological medicine (the reference medicine).

Both the biosimilar and its reference medicine will have the following similar characteristics (demonstrated using comprehensive comparability studies):

- *physicochemical*
- *biological*
- *immunological*
- *efficacy and safety.*

Due to the complexity of manufacturing biosimilars, the standard approach for demonstrating bioequivalence for most chemically derived medicinal products is not appropriate. More rigorous testing is required by the TGA for biosimilars than for generic chemical products. The TGA requires evidence for the safety and efficacy of the biosimilar for each indication approved for reference medicines that have multiple indications.

The recommendation of Pharmaceutical Benefits Advisory Committee for the listing of the biosimilar for infliximab

(Inflectra®) on the Pharmaceutical Benefits Scheme for a number of conditions came into effect in December 2015. This listing also includes the option for substitution at a pharmacy level providing the prescriber has not specified 'brand substitution not permitted' on the prescription.

Pharmacists should refer to sources of information about biosimilars such as information published on:

- the Pharmaceutical Benefits Scheme website (www.pbs.gov.au/info/general/biosimilars) which includes information about substitutable brands of infliximab where a prescriber has not specified 'brand substitution not permitted' on the prescription
- the Council of Australian Therapeutics Advisory Groups website (www.catag.org.au/wp-content/uploads/2012/08/OKA10429-CATAG-Overseeing-biosimilar-use-FINAL.pdf) which includes guiding principles for the governance of biological and biosimilar medicines in Australian hospitals, and
- the websites of pharmacist professional organisations.

Preceptor obligations: confirm provisional registration of interns

Pharmacy graduates are required to apply for and gain provisional registration and the Board's approval to undertake practice supervised by an approved preceptor. These requirements are set out in the Board's *Registration standard: Supervised practice arrangements*, published on its website under *Registration standards*.

Preceptors and employers must confirm that an intern's provisional registration and supervised practice arrangements are approved by the Board and published on the register before supervised practice may begin. Failure to comply with the standard may result in action by the Board. Any supervised practice undertaken without the Board's prior approval will not contribute to the period of supervised practice required for general registration.

CPD plans

The Board's revised *Registration standard: Continuing professional development* and *Guidelines on continuing professional development* came into effect on 1 December 2015, and introduced a requirement that pharmacists plan their CPD on an annual basis.

We remind pharmacists that you are required to meet the obligations of the revised CPD standard when you next renew your registration by 30 November 2016.

We have published some resources to help you.

A sample CPD plan/record to guide you in developing your CPD plan and recording your CPD activities is included in the revised FAQ. This CPD plan/record is also available as a blank template, which you can download and use in developing and maintaining your own CPD plan and record. Pharmacy professional organisations and CPD providers may also have useful resources.

The revised CPD standard and CPD guidelines are available in the *Registration standards* and *Codes, guidelines and policies* sections of our website.

National Scheme news

New video outlines objectives and role of the National Scheme

A new video (with an accompanying infographic) explaining the Australia-wide scheme that is in place to protect members of the public has recently been launched by AHPRA.

Aimed mainly at the community, the video outlines how AHPRA, working in partnership with the 14 National Boards, helps regulate Australia's 630,000-plus registered health practitioners through a national scheme.

The video explains how the National Scheme works and how patients are protected.

Both resources are available on the What we do page of the AHPRA website. The video can also be watched on AHPRA's YouTube channel.

Employer obligations: new awareness campaign

AHPRA has published a news item that outlines employers' obligations, and has advertisements running on LinkedIn and Facebook. This is the first step in the campaign, with many more activities to follow, including direct mail, paid print advertising, and advertising in community languages (for the public campaign).

The campaign will be rolled out in stages and has three target audiences and objectives:

1. Employers – check the register before employing someone, keep up to date with changes to registrations, make mandatory reports when required.
2. Practitioners – know your obligations as a registered health practitioner.
3. Public – check to see if your practitioner is registered.

More information is available in the AHPRA news item.

State and territory summaries now available – annual report 2014/15

State and territory summaries of the annual report are now available on the AHPRA website. The summaries provide a view of national data about our work to keep the public safe through a state or territory lens. We provide national comparisons to show how the state or territory compares with the national average and where possible, we provide two years of data, to identify and track trends over time.

More comprehensive data are in the 2014/15 annual report of AHPRA and the National Boards which was published in November 2015. The annual report also includes more detailed profession-specific information.

Later this month, the 14 National Boards will publish individual profession profiles on the AHPRA website, with links on their own websites. Keep an eye out for the pharmacy profession profile on the Pharmacy Board's website.

Dangers of button battery ingestion

From time to time the National Boards are asked to publicise important public health messages for health practitioners.

The Queensland Coroner's recent report into the death of a four-year-old girl, who died after swallowing a two-centimetre button battery, has highlighted the need for health practitioners to be aware of the dangers these products present if ingested, and to be better equipped to handle suspected cases.

When swallowed, lithium button batteries (also known as 'disc batteries') can become lodged in the oesophagus and the residual charge can cause electrolysis. This burns through tissue causing severe, irreversible damage.

Recognising battery ingestion can be difficult if the ingestion is not witnessed, as the child may present with non-specific symptoms such as poor feeding, irritability, fever, vomiting, drooling or cough. The ingestion of disc batteries requires urgent intervention.

Further information is available from the ACCC or advice can be obtained by ringing the Poisons Information Centre in Australia on 13 11 26.

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 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 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.

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