PHARMACY BOARD OF AUSTRALIA news
Issue 9 – October 2015
Pharmacy Board of Australia

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Chair's message

Welcome to the Pharmacy Board of Australia's (the Board) latest newsletter and my first as the Chair of the Board.

We delayed the distribution of the newsletter to provide an update on a number of items that were pending, and also so that we could acknowledge the contribution made by the outgoing Chair, Steve Marty.

As the Board's inaugural Chair, Steve's contribution both in the planning for, and in the transitioning of the various state Pharmacy Boards to the Pharmacy Board of Australia, under the National Registration and Accreditation Scheme (the National Scheme) has been outstanding. Steve's knowledge of pharmacy and pharmacist regulation is second to none, and his willingness to share this knowledge for the betterment of the profession and the protection of the public has brought him well-earned high praise. Thank you, Steve.

I'd also like to acknowledge the contributions of the other outgoing Board members - Gerry McInerney, Ian Huett and John Finlay. Like Steve, they have been inaugural Board members after distinguished service in their respective state boards before the National Scheme started. A special welcome also to incoming Board members – Ben Wilkins, Joy Hewitt, Mark Kirschbaum and Michael Piu.

William Kelly
Chair, Pharmacy Board of Australia

Board appointments announced

The Australian Health Workforce Ministerial Council (the Ministerial Council) recently announced new appointments and reappointments across 12 National Boards.

A full list of appointments for the National Boards is available in the Australian Health Workforce Ministerial Council communiqué from 6 July 2015.

Online renewal of registration is now open

Online renewal of registration is now open for pharmacists registered in Australia. If you are due to renew your general or non-practising registration by 30 November you can apply online now.

Last month the Board announced that it had limited the fee increase to below the national CPI of 1.3% for the registration period from 1 December 2015 to 30 November 2016. A fee schedule, including the fee arrangements for practitioners whose principal place of practice is NSW[1], is published on the Board's website.

The National Scheme is funded by practitioners' registration fees and there is no cross-subsidisation between professions.

A series of reminders to renew are being sent to practitioners by the Australian Health Practitioner Regulation Agency (AHPRA), on behalf of the Board. The email reminders include a link to online renewal.

Make sure your contact details are correct

Earlier this month, the Board published information on its website reminding pharmacists to update their contact details to ensure future email and hard copy reminders to renew registration. If you do not have your user ID you can complete an online enquiry form and select 'Online Services - Practitioner' as the category type. You may also need to reset your password.

Under the National Law[2], registered health practitioners are responsible for renewing their registration on time each year.

Last year 97.6 per cent of all health practitioner registration renewals due by 30 November (12 professions) were submitted online, an increase of 1.3 per cent.

Further information

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

- Registration standards
- Registration renewal
- Renewal FAQ

1 NSW is a co-regulatory jurisdiction.
2 The Health Practitioner Regulation National Law, as in force in each state and territory (the National Law).

Publication of revised guidelines for pharmacists

On 2 September the Board published revised guidelines that provide guidance to the profession on a range of issues.

We urge you to read the revised guidelines:

- *Guidelines for dispensing of medicines*
- *Guidelines on practice-specific issues*
    - Guideline 1 *Reference texts for pharmacists*
- *Guidelines on dose administration aids and staged supply of dispensed medicines, and*
- *Guidelines for proprietor pharmacists.*

The guidelines were subject to wide-ranging consultation and will take effect on **7 December 2015**. They have been published now so you can become familiar with their content before implementation.

Changes include renaming the titles of guidelines to better reflect content, and restructuring of some of the guidelines for ease of reading.

Please review the new guidelines and familiarise yourself with all changes to ensure you comply in your practice from 7 December.

Under section 41 of the National Law, Board guidelines can be used in disciplinary proceedings, under the National Law or law of a co-regulatory jurisdiction, as evidence of what constitutes appropriate professional conduct or practice for pharmacists.

When considering notifications (complaints) against pharmacists, the Board may give consideration to whether a breach of Board guidelines has taken place.

Some of the changes to the guidelines include:

Guidelines for dispensing of medicines

- Guideline 5 *Extemporaneous dispensing* has been removed from the guidelines and published as a separate set of guidelines titled *Guidelines on compounding of medicines.*
- Inclusion of a new guideline, Guideline 9.2 *Protection of electronic data*, which addresses the specific risks to pharmacists' electronically stored data.
- Further guidance on the use of scanners when dispensing medicines in Guideline 10.1 *Scanners.*

Guidelines on practice-specific issues

- Inclusion of additional options for the required reference texts for pharmacists in Guideline 1 *Reference texts for pharmacists. (Note: On 16 September 2015, the revised Guideline 1 was updated to remove the reference text 'Drug interactions analysis and management, Hansten and Horn' as an option under e) 'a drug interactions reference (updated at least quarterly)', as this reference is no longer in publication.)*
- Additional guidance on the provision of complementary and alternative medicines at a pharmacy in Guideline 5 *Complementary and alternative medicines*, including guidance that pharmacists:
    - should provide products of proven safety and quality
    - should provide relevant accompanying advice to assist patients in making an informed choice, and
    - where appropriate should record the supply.

Guidelines on dose administration aids and staged supply of dispensed medicines

- These guidelines provide additional guidance, some of which includes:
    - labelling of dose administration aids (DAAs)
    - packing of DAAs by a third party
    - supply of oral cytotoxic and other hazardous medicines into DAAs, and
    - initiation of periodic administration of a dispensed medicine.

Guidelines for proprietor pharmacists

- These guidelines reflect the current legislative requirements in relation to the registration type that proprietors must hold in a jurisdiction. This is supported by a revised statement *Registration type required by proprietor pharmacists* (replaces the retired statement *Clarification on registration type required by proprietors of pharmacies),* published on the Board's website.
- Provision of additional guidance on the responsibilities of proprietor pharmacists, including those relating to advertising, and facilitating employee pharmacists to meet the Board's registration standards.

The revised guidelines are available in the Codes, guidelines and policies section of the Board's website.

Compounding of medicines

In its April 2015 communiqué the Board advised that the *Guidelines on compounding of medicines* are in effect, with the exception of the section *Expiry of compounded parenteral medicines,* which has been postponed for three months. Postponing this section will provide additional time to consider feedback and information on the proposed guidance about the expiry of compounded medicines, which needs further investigation and review.

The Board is consulting with the Therapeutic Goods Administration (TGA) about the feedback received and will provide further information to clarify the proposed guidance in its communiqué and next newsletter.

The Board published frequently asked questions (FAQ) to give pharmacists and the public more information and clarification on a range of issues relating to the compounding of medicines. The FAQ are published on the FAQ and fact sheets page on the Board's website.

The *Guidelines on compounding of medicines* were subject to wide-ranging consultation and replace Guideline 5 *Extemporaneous dispensing (compounding)* from the Board's *Guidelines for dispensing of medicines.* Guideline 5 was in effect until 27 April 2015. The current guidelines are published on the Codes, guidelines and policies page on the Board's website.

See the TGA website for information for compounding pharmacies on the legislative requirements for advertising extemporaneously compounded medicines to consumers.

Quarterly registration data

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

At June 2015, there were 29,014 registered pharmacists, shown below by registration type:

- 26,179 – general registration
- 1,815 – provisional registration
- 14 – limited registration, and
- 1,006 – non-practising registration.

The quarterly registration data at June 2015 are published on the Board's website under About>Statistics. The report includes a number of statistical breakdowns.

Accessing the national register of practitioners

The online national register of practitioners has accurate, up-to-date information about the registration status of all registered health practitioners in Australia. It is an important way the National Scheme helps keep the public safe.

A copy of Top tips: Using the register for public safety checks can be downloaded from AHPRA's website.

Large-scale employers can also enquire with AHPRA about the online subscription service where an employer can request the publicly available registration details of multiple practitioners. On the enquiry form, please select 'Online Services - Employer' in the drop down menu for 'category of enquiry'. After submitting your request, you will be contacted directly by an AHPRA staff member to validate your identity and eligibility to use the service.

Practice advice

Cautionary advisory labels

The Australian pharmaceutical formulary and handbook (APF) includes wording for a range of standard cautionary advisory labels (CAL) and provides guidance on their use for specific medicines.

The Board's published guidance for pharmacists outlines the need to maintain up-to-date essential references (including the APF), which must be readily accessible to pharmacists in practice (refer Guideline 1 – References, Guidelines on practice-specific issues).

The Board has also published guidance on the use of CAL in Guideline 7.3 *Ancillary labels*, Guidelines for dispensing of medicines, which states:

'Some ancillary labels are mandatory — these are listed in the *Standard for the uniform scheduling of medicines and poisons* (SUSMP). The routine use of other ancillary labels in the *Australian pharmaceutical formulary and handbook* is recommended having regard to each patient's circumstances.'

The Pharmaceutical Society of Australia (PSA) recently expressed concerns to the Board that a quality audit of CAL recommendations contained within dispensing software revealed a significant number of those were not aligned with the recommendations of the 23rd edition of the APF.

Before handing out dispensed medicines, you must be satisfied that the correct information, including the appropriate CAL for the relevant medicine, has been provided. The CAL recommendations in the APF should be followed, and you should not rely on dispensing software as errors may pose significant risk to patient outcomes.

Pharmacists who fail to provide correct and required information about dispensed medicines to patients may face sanctions that can be imposed under the National Law for unprofessional conduct.

Supply of scheduled medicines for the treatment of animals

Pharmacists are reminded to make sure they comply with state and territory legal requirements for the supply of scheduled medicines for the treatment of animals.

You must comply with the requirements in relation to the supply of such prescribed medicines which are limited to the use in the treatment of an individual (named) animal and should be labelled as such.

Where medicines are prescribed by a veterinary surgeon/practitioner for use in a group or herd of animals, the prescriber is responsible for ensuring that this supply is made in accordance with legislative requirements in their jurisdiction of practice. The prescriber is responsible for the labelling and supply of medication prescribed for a group or herd of animals.

Case studies

The Notifications Committee of the Board has provided the de-identified case studies below to encourage pharmacists to avoid similar incidents in the future.

Case study 1 – Purchase of products from an internet supplier

The Notifications Committee of the Board has provided the de-identified case study below to encourage pharmacists to avoid similar incidents in the future.

The allegation

A notifier alleged that a pharmacist purchased OxyElite Pro capsules from a supplier in the United States and supplied the product to patients of the practitioner's pharmacy.

The issues

OxyElite Pro capsules contain therapeutic quantities of yohimbine, which is a prescription-only substance in Australia, a prohibited import under Customs legislation and not approved for supply in any registered medicine in Australia. It has been the subject of a TGA safety alert since 8 July 2012.

The pharmacist was aware that the supply of yohimbine was prohibited in Australia, but was not aware of any safety alerts concerning OxyElite Pro capsules.

Since the incident, the practitioner advised that a number of measures had been put in place in the pharmacy to prevent a similar incident occurring in the future, including:

- a requirement to carry out a thorough check of all items before an internet order is placed, including a TGA check
- receiving medicine safety updates and alerts by email from the TGA
- the ability to access the Australian adverse drug reactions bulletin
- subscribing to www.australianprescriber.com, which has a section 'Medicines Safety Update', and
- acting on individual alerts, such as Guild Fax stream.

The outcome

The pharmacist was cautioned and a condition was imposed on their registration requiring them to attend an education course relevant to dispensing medicines.

Lessons to be learnt

Pharmacists must comply with all legal obligations when medication is supplied to the public and access any relevant information about the safety of medicines. Particular care should be taken when importing medicines to make sure that legislation controlling the importation of therapeutic drugs and substances is adhered to, which may include determining whether a permit to import a substance is required.

Case study 2 – Drugs in pregnancy and breastfeeding

A recent notification highlighted the importance of giving appropriate advice about medicines used during pregnancy or while breastfeeding.

In this particular case, a pregnant woman was responsible for administration of the dispensed medicine (methotrexate) to the patient, but was not advised about the necessary precautions when handling methotrexate. Appropriate information must be provided in such circumstances to minimise risks to individuals handling such medicines.

Advice about pregnancy risk categories is available in a range of reference texts listed in Guideline 1 of the Board's Guidelines on practice-specific issues. However, patients and their agents require more information than the pregnancy risk category assigned to a drug.

The 'Clinical monographs' section of the current edition of the *Australian pharmaceutical formulary and handbook* states:

> 'Legal considerations have sometimes resulted in sponsor companies applying a more restrictive category than can be justified by the available data. When considering the use of any medicine for a woman who is pregnant, the pharmacist should always consider alternative options, the risks associated with not treating a condition, whether dose adjustments are required, potential adverse effects on the foetus, and any monitoring that may be required.'

Further information on this subject can be found in:

- *Pregnancy and breastfeeding medicines guide* (Royal Women's Hospital, Melbourne)
- *Australian medicines handbook*
- approved product information for the medicine, and
- the Prescribing medicines in pregnancy database on the TGA website.

Pharmacists must ensure that they provide suitable explanation and advice about the safety of medicines in pregnancy and breastfeeding that is applicable to and understood by patients or their agents. This relies upon the interpretation of information available from the wide range of references and other resources that pharmacists have access to, and may require discussion of the available options with the prescriber to ensure that a satisfactory outcome for the patient is achieved.

National Scheme news

Criminal history and English language skills registration standards have been revised

The registration standards for criminal history and English language skills have been revised following consultation and were approved by the Ministerial Council. Both registration standards came into effect on 1 July 2015.

Further information is available on the Board's website.

Health ministers' response to National Scheme review report

The Ministerial Council met on 7 August 2015 at the COAG Health Council meeting to consider the final report of the independent review of the National Scheme.

The purpose of the independent review was to identify what is working well in the National Scheme and the opportunities to improve and strengthen the operation of the scheme to regulate health professions to protect the public.

Ministers expressed strong support for the work of the National Scheme, noted that it was now embedded in the health system and was among the most significant and effective reforms of health profession regulation in Australia and internationally.

More information about the review can be found on the COAG Health Council website and on AHPRA's website.

Royal Commission into Institutional Responses to Child Sexual Abuse

The Board and AHPRA have been following the Royal Commission into Institutional Responses to Child Sexual Abuse and its implications for the regulation of health practitioners. The issues raised in the royal commission hearings are serious and disturbing.

The Board and AHPRA are committed to learning from the evidence before the royal commission and its findings and are taking action to make sure our regulatory system is responsive to anyone who has been sexually abused by a registered health practitioner, who comes forward.

If you have a concern about a health practitioner call:

- AHPRA on 1300 419 495
- NSW – 1800 043 159, or
- Qld – 133 646 (133 OHO).

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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