PHARMACY BOARD OF AUSTRALIA news
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Pharmacy Board of Australia

Contents

Chair's message

Welcome to the final newsletter for 2015 from the Pharmacy Board of Australia (the Board). In this newsletter we provide an update on important topics such as practice advice, the Board's annual report and registration renewal.

Recently we released our 2014/15 annual report, which includes details of the Board's achievements and priorities during the financial year. In coming months, we will also publish a profession-specific profile.

I would also like to remind you all that the registration renewal date for pharmacists with general or non-practising registration was 30 November 2015. If you haven't already renewed your registration, please do so as soon as possible.

We have started preparing for a busy 2016 and I look forward to working with you all as we continue to work on improving and strengthening the National Registration and Accreditation Scheme (the National Scheme), driving operational excellence and protecting the public.

On behalf of the National Board, I wish you all a safe and happy festive season.

William Kelly
Chair, Pharmacy Board of Australia

Compounding of medicines

In its April 2015 communiqué the Board advised that the *Guidelines on compounding of medicines* (the guidelines) are in effect, with the exception of the section *Expiry of compounded parenteral medicines.* This section has been postponed to allow additional time to consider feedback and information on the proposed guidance about the expiry of compounded parenteral medicines that needed further investigation and review.

The Board is currently reviewing feedback on draft revised proposals before a period of further public consultation, which is due to take place in early 2016.

The guidelines are published on the Codes, Guidelines and Policies page on the Board's website. Frequently asked questions (FAQ) are published on the FAQ and Fact Sheets page on the Board's website.

Video and PowerPoint for pharmacy students and graduates released

The Board has launched a three minute video which outlines the steps graduates need to take to gain provisional registration and complete an internship to be eligible to apply for general registration.

The video is a quick and easy way for graduates and students close to finishing their studies to find out what they need to do before applying for provisional registration and starting their supervised practice.

In addition to outlining the standards graduates must meet to become registered, the video also includes information about the ongoing obligations for pharmacists.

The Board has also released a PowerPoint, 'Provisional registration for internship – Requirements and responsibilities'. It explains in further detail the information touched on in the video.

The video and PowerPoint are available on the Internships page of the Board's website.

Publication of revised standards and CPD guidelines for pharmacists

On 1 November 2015 the Board published the following revised registration standards and guidelines for pharmacists:

- *Registration standard: Continuing professional development (CPD)*
- *Guidelines on continuing professional development*
- *Registration standard: Recency of practice (RoP)*
- *Registration standard: Supervised practice arrangements, and*
- *Registration standard: Examinations for eligibility for general registration.*

On 1 December 2015, these replaced the previous standards and guidelines which had been in place since 1 July 2010 when the National Scheme started.

Pharmacists holding general registration will need to meet the requirements of the revised CPD and RoP standards by the next registration renewal period, on 30 November 2016.

Changes to the revised standards and guidelines are minor and expected to have limited effect on pharmacists. These are detailed in a summary of changes document published on the Board's website.

Some of the changes include:

- the introduction of a requirement that all pharmacists develop a CPD plan to assist in identifying areas in need of further development, (in the revised CPD standard and guidelines), and
- the inclusion of an additional option for applicants for registration to meet the minimum practice requirements of 150 hours during the previous 12 months, in addition to the current option of 450 hours during the previous three years, (in the revised RoP standard).

The wording and structure of the revised standards and CPD guidelines have been simplified, and have additional information to help pharmacists understand the minimum requirements, including the consequences if a pharmacist does not meet the requirements.

Revised FAQ on CPD, an *Intern pharmacist and preceptor guide* and FAQ for pharmacy interns and preceptors will also be published on the Board's website in the coming weeks. These will provide further guidance for pharmacists and interns, to assist them in complying with the Board's requirements.

The revised standards were approved by the Australian Health Workforce Ministerial Council (the Ministerial Council) on 27 August 2015 and were part of a scheduled review of standards. A public consultation was held as part of the review. National Boards have published consultation reports providing a summary of the consultation processes, rationale for any changes and proposed way forward, including areas where further work is planned. The submissions to the public consultation are published on the Board's website.

A revised *Registration standard: Professional indemnity insurance (PII) arrangements* was also published on the Board's website last week, with an implementation date of 1 July 2016. Pharmacists will need to meet the requirements of the revised standard either:

- by the time they next renew their PII arrangements policy, or
- by their next renewal of registration which is due by 30 November 2016, whichever is sooner.

This standard continues to set a minimum amount of cover of $20 million, which reflects the industry standard. There are some minor changes to the requirements for pharmacists, with the revised standard specifically requiring policies to have retroactive cover and automatic reinstatement.

The revised standard also contains 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.

Revised guidelines for pharmacists in effect

Revised guidelines for pharmacists published in September came into effect on 7 December 2015.

The revised guidelines provide guidance to the profession on a range of issues. The guidelines were released early so that pharmacists can become familiar with their content before implementation.

The revised guidelines now in effect are:

- *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.*

Some of the changes to the guidelines were highlighted by the Board in September.

Under section 41 of the Health Practitioner Regulation Law, as in force in each state and territory (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.

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

Practice advice

Returned drugs of dependence to pharmacies

Concern has recently been expressed to the Board regarding the diversion of Schedule 8 poisons (Controlled Drugs) from Return Unwanted Medicines (RUM) bins in community pharmacies by pharmacists or other pharmacy employees. This may be for self-administration purposes, or for unlawful diversion to other persons, both of which pose a risk to public safety.

The underlying issue relates to Schedule 8 medicines being placed in the RUM bin without any attempt to make it difficult to recover them and make them unusable.

Pharmacists practising in community, hospital or other pharmacy practice settings, are reminded that they must at all times comply with state and territory legal requirements when they accept from the public unwanted medicines for safe disposal. This includes any requirements which specifically relate to the recording, storage and destruction of Schedule 8 poisons.

The Board notes that these requirements may vary between jurisdictions through state-based drugs and poisons legislation, and strongly urges pharmacists to ensure they are familiar with their jurisdictional requirements to ensure that they are compliant in their practice.

Guideline 14 Return of unwanted medicines in the Board's revised Guidelines for dispensing of medicines provides additional guidance to pharmacists on returned medicines, and encourages pharmacists in community pharmacy practice to participate in available programs, such as the RUM project.

This guideline states - 'Pharmacists are referred to the detailed procedures relating to the return and disposal of unwanted medicines, including Schedule 8 poisons (Controlled Drugs), needles, other sharps and cytotoxic products available at www.returnmed.com.au.'

The Board notes that in hospital pharmacy practice, local policies and protocols exist, but reminds pharmacists working in this practice environment that state and territory legal requirements must also be complied with.

Quarterly registration data

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

At September 2015, there were a total of 29,150 registered pharmacists comprising the following number of registrants according to registration type:

- 26,377 – general registration
- 1,750 – provisional registration
- 14 – limited registration, and
- 1,009 – non-practising registration.

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

Approval of supervised practice

Intern pharmacists must undertake a total of 1824 hours of Board approved supervised practice in accordance with the Board's *Registration standard: Supervised practice arrangements* (the standard).

Over the 12 months ending 30 June 2015, the Board's Registration and Examinations Committee dealt with 16 general registration applicants from intern pharmacists who did not seek the Board's approval of their supervised practice hours before starting and therefore had not complied with the standard. This put them at risk of not meeting the requirements for general registration.

Information about supervised practice is also outlined in the preceptor and intern guides available on the Board's website.

Pharmacy graduates must hold provisional registration and obtain the Board's approval of their supervised practice arrangements before starting their internships and enrolling in an intern training program.

The role of the preceptor is set out in the *Preceptor guide* which states that an 'approved supervised practice position must be secured (by the graduate) before enrolling in an Intern Training Program'.

Preceptors need to ensure that an intern pharmacist holds provisional registration and has obtained prior approval from the Board for the proposed supervision arrangements. This can be confirmed by searching the online national register of practitioners.

In addition, 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.

Tribunal decisions

The State Administrative Tribunal of Western Australia (the tribunal) has reprimanded pharmacist Mr David Brewster, cancelled his registration and disqualified him from reapplying for registration for one year.

The Board had referred Mr Brewster to the tribunal because of concerns about his dispensing drugs of dependence including anabolic steroids and Schedule 4 medicines. The Board suspended Mr Brewster's registration in October 2014, as an interim step to keep the public safe, pending other enquiries.

Ahead of the tribunal hearing, Mr Brewster admitted to professional misconduct for:

- twice between August and November 2013, supplying labels to act as dispensing labels for Stilnox and alprazolam medications to a person, for use on containers of medications held by the person but which were not dispensed by him or Hollywood Pharmacy

- supplying large volumes of anabolic steroids without valid prescriptions and notification to the proper authorities
- selling or supplying pseudoephedrine products without the relevant documentation being completed, in breach of the Poisons Regulations 1965
- importing Schedule 4 medicines from overseas suppliers between June 2013 and July 2014, including modafinil 200mg tablets, which bypassed the Australian Therapeutic Goods Framework and were not on the Australian Register of Therapeutic Goods, in breach of section 19B of the Therapeutic Goods Act 1989; and
- making no record of the supply of the modafinil to an unidentified WA based doctor.

On 25 August 2015, the Tribunal found Mr Brewster engaged in professional misconduct, cancelled his registration, reprimanded him and ordered him to pay $8,000 in costs to the Board.

The reasons for the tribunal's decision are on the State Administrative Tribunal (WA) website and will be published on AustLII.

National Scheme news

2014/15 National Scheme annual report

The Australian Health Practitioner Regulation Agency (AHPRA) and the National Boards have released their 2014/15 annual report on the National Scheme, providing a comprehensive record of the operations of the National Scheme for the 12 months ending 30 June 2015.

The annual report provides a national snapshot of the work and finances of the National Scheme and is tabled in the parliaments of each state and territory and the Commonwealth.

AHPRA and the National Boards will also shortly publish summaries of our work regulating health practitioners in every state and territory, and profession-specific profiles.

For more information, please read the news item AHPRA's website.

Pharmacy profession profile

In the coming months, the Board will publish a report of its work in regulating the pharmacy profession in the National Scheme during 2014/15.

The report provides a profession-specific view of the Board's work to manage risk to the public and regulate the profession in the public interest. It is a profile of regulation at work in Australia for the 12 months ending 30 June 2015.

The data in this report are drawn from data published in the 2014/15 annual report of AHPRA and the National Boards, reporting on the National Scheme.

New RACGP guide on prescribing benzodiazepines

The Royal Australian College of General Practitioners (RACGP) has released a new guide for general practitioners on prescribing benzodiazepines, focusing on patient-centred care, accountable prescribing and harm reduction. Also available is a clinical governance framework for prescribing drugs of dependence in general practice, which provides practices with principles, strategies and tools in relation to prescribing drugs of dependence. These guides, which may be of value to pharmacists in their practice, are available on the RACGP website.

Changes to Medicines Australia code of conduct affecting health practitioners

Pharmacists should be aware of changes to the Medicines Australia code of conduct (the code). Medicines Australia is a membership organisation for pharmaceutical companies in Australia. The code sets standards for the advertising and promotion of prescription medicines and applies to all member organisations. The revised code requires member companies to publicly disclose payments made to health professionals for their expert service or when financial support is provided for education purposes, including airfares, accommodation and conference registration fees.

The new requirements in the code came into effect on 1 October 2015 and reporting of all payments will be mandatory from 1 October 2016. More information is available on Medicines Australia's website.

Queensland complaints data have been published

AHPRA and the National Boards have published detailed performance data about notifications management in Queensland.

A co-regulatory system has been in place in Queensland since July 2014 and all complaints about Queensland registered health practitioners are received by the Office of the Health Ombudsman (OHO). The Health Ombudsman is responsible for managing serious complaints relating to the health, conduct and performance of health practitioners in Queensland, and determines which complaints go to AHPRA and the National Boards after assessing their severity.

AHPRA provides quarterly data to the OHO about its performance in managing the complaints which come to AHPRA and the National Boards from the OHO. These data provide quantitative information about the number of complaints received and timelines for managing them.

The first report, which was published in May, includes detailed performance data about notifications management for the first three quarters from 1 July 2014 and 31 March 2015.

Analysis of these data, detailing matters managed by AHPRA and the National Boards, indicates:

- complaint referral patterns from the OHO to AHPRA are variable month to month
- on early trends, AHPRA is receiving 50 per cent fewer complaints than for the comparable period in 2013/14. This suggests the OHO is not accepting, is retaining and/or is closing most matters that the Ombudsman considers do not warrant further action. Of those we manage, more than 70 per cent require further regulatory action, and
- investigation timelines continue to be a major focus for AHPRA and the Boards. Sixty seven of the matters open with AHPRA for longer than 18 months are about 25 practitioners. Multiple complaints about the same practitioner require more complex investigations.

AHPRA continues to focus on decreasing the time it takes to investigate matters, finalising more old investigations and improving the notifier and practitioner experience.

AHPRA will publish more national performance data throughout this financial year.

The Queensland report is published on the AHPRA website Statistics page.

Improving monitoring of conditions on practitioner registration

AHPRA has welcomed calls for stringent monitoring and swift detection of breaches in compliance by registered health practitioners with restrictions on their registration.

On 24 March 2015, the OHO published a report recommending a range of initiatives to strengthen monitoring and compliance in Queensland and the National Scheme.

'Regulation is all about managing risk to patients and we welcome all suggestions to help improve our work in public safety,' AHPRA CEO Martin Fletcher said.

'These recommendations affirm the sweeping changes we have already initiated to strengthen our compliance and monitoring program.'

AHPRA's detailed response to the OHO and the recommendations in the report is published on its website Corporate publications page.

Since July 2014, health complaints management in Queensland for registered health practitioners has involved a partnership between National Boards, AHPRA and the OHO.

Improvements to compliance monitoring add to the overhaul of complaints management in Queensland that started in 2012. Recent initiatives include preparation for stricter drug and alcohol screening announced in February 2015, the appointment of a national compliance manager and stronger national coordination of the compliance function.

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

National drug screening protocol

There are health practitioners with a history of substance misuse who have restrictions placed on their registration. These restrictions are generally designed to keep the public safe while the practitioner remains in practice.

When restrictions are placed on a health practitioner's registration, AHPRA monitors the practitioner to make sure they are complying with the restrictions. This process is referred to as 'monitoring and compliance'.

From November 2015, all health practitioners who have restrictions placed on their registration by the Board as a result of past substance misuse will have routine quarterly hair testing, in addition to random urine testing. Routine hair testing provides additional information about the use of a wide range of drugs, over a longer time period. It therefore provides greater assurance to the Board that the practitioner is not impaired as a result of ongoing substance misuse.

The introduction of routine hair testing is based on expert advice about modern drug screening methods. Using contemporary scientific evidence and the advice of an expert panel, National Boards and AHPRA will manage the risk associated with practitioners with a history of substance misuse.

Funding

As required by the National Law, National Boards will pay the costs of testing required to assess a practitioner, where that testing is required as part of a health assessment required by the Board.

Health practitioners will pay for ongoing screening costs, including the cost of hair testing which is currently $825 including GST per test.

This funding model, which requires health practitioners to pay for the cost of ongoing screening, recognises that health practitioners who have restrictions on their registration linked to past substance misuse are able to continue to work while being monitored and therefore can earn an income.

Boards have approved a policy whereby in instances of proven financial hardship, they may bear the cost of ongoing screening.

More information

More about the assessment and management of practitioners whose health impairment may pose a risk to the health and safety of the public is published online:

- media release about the strengthening of national drug screening (16 February 2015)
- information about the notifications process
- fact sheet about monitoring and compliance, and
- fact sheet about health assessments.

AHPRA actions to improve consumer and practitioner experience

Improving the experience of people who have made a notification has been a focus for AHPRA and the National Boards since early last year, when the Health Issues Centre of Victoria (HIC) was commissioned to conduct targeted research into the consumer experience when making a notification.

Since then a raft of changes to address the issues this research raised have been made, in particular to make written communication clearer and easier to understand.

Earlier this year, senior leaders from AHPRA and the Medical Board of Australia (MBA) met Australian Medical Association (AMA) leaders about the way notifications are managed – including decision-making protocols, guidance and policies.

Key issues include the time it takes for a notification to go through the process; the tone and clarity of communication; the need to better explain how the process works and why, and greater transparency wherever legally possible.

AHPRA will continue working on addressing the HIC's recommendations, and on other activities that will improve the overall experience of both consumers and practitioners who are the subject of a notification.

The latest update on this work has been published on our website at Improving our work.

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: Bill Kelly, Chair, Pharmacy Board of Australia, GPO Box 9958, Melbourne, VIC 3001.

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