

Contents

Chair's message	1
Revised competency standards	1
Compounding guidelines update	2
Update on the review of the Code of conduct	2
Board webinar for final year pharmacy students	2
Practice advice	2
National Health (Pharmaceutical Benefits) Regulations 2017	2

Biosimilar medicines awareness campaign: eterncept listed on the PBS	2
Case summaries	2
Tribunal and court decisions	3
Former pharmacist fined for holding himself out as a registered pharmacist	3
National Scheme news	3
Scheduled Medicines Expert Committee appointed	3
Keep in touch with the Board	4

Chair's message

Welcome to the latest edition of the Pharmacy Board of Australia's newsletter. There have been a number of developments affecting pharmacists' practice since the last newsletter and I'd like to draw your attention to one of these, the release of the *National competency standards framework for pharmacists in Australia 2016*, which all pharmacists will be expected to be familiar with and able to use. Further advice and support tools will be provided in the near future to help you during the transition period.

I am also pleased to announce that the Board is nearing completion of its revision of its guidance on the expiry of compounded parenteral medicines. We expect to publish that revised guidance in the coming weeks, and you will receive a separate communication from the Board about this shortly.

Last, on behalf of the Board I wanted to thank all pharmacists who took part in the Board's meet and greet event held in Adelaide on Thursday 23 March 2017, which coincided with the March Board meeting held the following day. More than 50 students, registered local community and hospital-based pharmacists and pharmacy stakeholders from South Australia attended the event, which included a panel discussion on 'Emerging areas of pharmacy practice' facilitated by Emeritus Professor Lloyd Sansom. Thanks also to panelists Adam Phillips, National Manager, Pharmacy Innovation and Quality, TerryWhite Chemmart, Peter Halstead, Pharmacy Regulation Authority SA, Steve Morris, Executive Director SA

Pharmacy/Chief Pharmacist SA Health, and Debra Rowett, Director, Drug and Therapeutics Information Service.

There was some very interesting discussion on topics such as the rapid transition of eHealth, better use of health data, adapting the pharmacy services provided to what consumers want and need and reducing fragmentation in the healthcare team.

William Kelly

Chair, Pharmacy Board of Australia

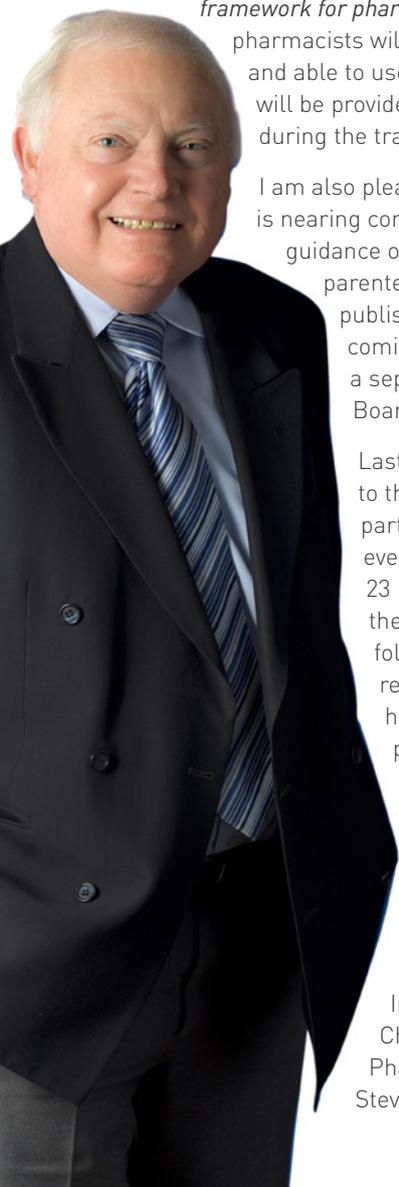
Revised competency standards

In May the Pharmacy Practitioner Development Committee (PPDC), on behalf of its member organisations, announced the release of the *National competency standards framework for pharmacists in Australia 2016*.

The 2016 framework consists of five domains covering *Professionalism and ethics, Communication and collaboration, Medicines management and patient care, Leadership and management* and *Education and research*, with the first two being universally applicable to all pharmacists.

In its 31 May 2017 [media release](#), the PPDC advised that it is currently developing practice tools to support pharmacists during the implementation of the revised framework, and is considering an appropriate transition timeframe, recognising that the 2010 framework is well embedded across all facets of the profession including pharmacists' continuing professional development (CPD) plans. Although the revised framework has been published, during the current CPD recording period (ending 30 September 2017) the current competency standards (2010 version) apply.

The Board in collaboration with the Australian Pharmacy Council (APC) will determine and provide further advice on the implementation of the revised framework with respect to the assessment of interns.



Compounding guidelines update

The Board's work to revise the currently postponed section 'Expiry of compounded parenteral medicines' of the [Guidelines on compounding of medicines](#) (compounding guidelines) is nearing completion, with revised guidance anticipated to be published in the coming weeks. An implementation period will be announced (to be advised). To coincide with publication of the guidance, we will also publish updated FAQ that will address issues about compounded injectable medicines.

The Board will provide pharmacists with details once the revised guidance has been published. In the meantime, the Board reminds you that when compounding medicines you are expected to comply with the published compounding guidelines, which require you to:

- comply with all relevant practice standards, guidelines and legislation
- have good clinical and pharmaceutical evidence to support the quality, stability (including an appropriate 'in use expiry' and/or beyond use date), safety, efficacy and rationality of any extemporaneous formulation
- compound a medicine only where an appropriate commercial product is unavailable or unsuitable, and
- use sound judgement based on current clinical and pharmaceutical knowledge and risk assessment, before deciding whether to prepare a formulation for which there is no precedent in a reputable reference, and have documented evidence for your decision to compound.

Update on the review of the Code of conduct

The Board's [Code of conduct](#) (the Code) is also common to ten other National Boards (Aboriginal and Torres Strait Islander Health Practice, Chinese Medicine, Chiropractic, Dental, Medical Radiation Practice, Occupational Therapy, Optometry, Osteopathy, Physiotherapy and Podiatry), with some minor profession-specific changes for some Boards including Pharmacy.

The Code is a regulatory document that provides an overarching guide to support and inform good practice and to assist practitioners, National Boards, employers, healthcare users and other stakeholders to understand what good practice involves. It seeks to assist and support practitioners to deliver safe and effective health services within an ethical framework.

As the Code was last published in March 2014, the Board has started a scheduled review with other National Boards that use the Code. The review will draw on best available research and data and involve additional stakeholder consultation and engagement.

The review is still at an early research phase. However, we are already considering how we can maximise opportunities for input when the consultation stage of the review starts. In addition to public consultation, we intend to use our website and other social media to inform pharmacists about how they can contribute to the review. Opportunities to be involved will be highlighted in upcoming Board communiqués and newsletters.

Board webinar for final year pharmacy students

The Board will be hosting a webinar for final year pharmacy students on Wednesday 6 September 2017, which will help them in their transition from student to provisional registration and in understanding the Board's requirements during the internship period.

It will be hosted by Brett Simmonds, the Deputy Chair of the Board and practitioner member from Queensland. There will be a Q&A session at the end of the webinar which is an opportunity for participants to directly interact with Brett and AHPRA staff. We will invite final year students to register for the webinar closer to the scheduled date.

Practice advice

National Health (Pharmaceutical Benefits) Regulations 2017

The National Health (Pharmaceutical Benefits) Regulations 2017 are now in effect, replacing the 1960 regulations.

Regulation 24, *Circumstances in which quantity of repeated supply can be directed to be supplied on one occasion*, which permits pharmacists to supply multiple repeats of a medicine at the one time as a pharmaceutical benefit, is now Regulation 49 in the new regulations. This change has been reflected in Guideline 3: *Dispensing multiple repeat prescriptions at one time* of the Board's published [Guidelines for dispensing of medicines](#).

Biosimilar medicines awareness campaign: etanercept listed on the PBS

The Brenzys® brand of etanercept was listed on the PBS from 1 April 2017. It is the first biosimilar medicine in Australia to be available through community pharmacies as a self-administered therapy substitutable ('a' flagged) with the Enbrel® brand of etanercept. Etanercept treats a range of autoimmune inflammatory conditions.

The Department of Health has published factsheets about the Brenzys listing, available at www.health.gov.au/biosimilars. The website also includes brochures and other detailed information about biosimilar medicines.

A list of biological medicines currently listed on the PBS is also available on the [PBS website](#) via the *Browse the PBS tab*.

Case summaries

Circumstances when a compounded medicine should be prepared

The Board recently considered notifications that alleged that pharmacists had not complied with the Board's [Guidelines on compounding of medicines](#) (compounding guidelines).

The compounding guidelines state:

'A compounded medicine should be prepared only in circumstances 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 compounding of a medicine (whether prescribed or not) that 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, should not take place. In the case that such a medicine has been prescribed, the pharmacist should notify the prescriber that this medicine cannot be compounded under these circumstances.'

The Board identified examples of medicines that were compounded by pharmacists without proper regard to this guidance in that the compounding occurred when:

- an appropriate commercial product was available, and/or
- the formulation of the compounded medicine was a close formulation to an available and suitable commercial product which is listed on the Australian Register of Therapeutic Goods (ARTG), and would not be likely to produce a different therapeutic outcome to the commercial product.

In the case of the latter issue, there was no evidence that an added ingredient (not present in the commercially available product) needed to be compounded in the same dose form or that it would provide any additional therapeutic effect. Also, the pharmacist did not contact the prescriber to discuss whether the prescribed medicine should be compounded and instead supplied the medicine as prescribed.

Several pharmacists were cautioned in relation to their practice, and advised to ensure that they comply with the Board's compounding guidelines at all times when compounding medicines. In each case, the reasons for the Board's decision to issue a caution (as opposed to taking other action available to the Board under the National Law), included that the pharmacist had:

- reviewed their practice and reflected on the Board's compounding guidelines, following receipt of the notification
- admitted to previously being in breach of the compounding guidelines, and
- demonstrated insight into their practice and was contrite in their response.

Tribunal and court decisions

There are important lessons for registered pharmacists from tribunal and court decisions. The Board refers the most serious concerns to tribunals in each state and territory. Cases published since March 2017 include:

Former pharmacist fined for holding himself out as a registered pharmacist

A former pharmacist in Western Australia has been convicted of holding himself out as a registered pharmacist while not being registered under the National Law.

Mr Brian Geoffrey Donegan was sentenced at Geraldton Magistrates Court after he pleaded guilty to seven charges. The charges, which were brought by AHPRA, relate to holding himself out, and claiming to be a registered pharmacist while not being registered, and on two occasions using the protected title 'pharmacist' while not being registered to do so under the National Law.

Mr Donegan admitted to working as the sole pharmacist on duty at Northampton Pharmacy between October 2015 and June 2016. In this period, he admitted to dispensing both Schedule 4 and Schedule 8 medicines to patients while not holding registration as a pharmacist.

Mr Donegan admitted that on two separate occasions, he used the protected title 'pharmacist' by allowing his name to be displayed on a 'pharmacist on duty' sign. He also admitted to submitting, to the owner of Northampton Pharmacy, a fraudulent certificate of registration stating that he held unrestricted registration at the relevant time.

The National Law protects the public by ensuring that only registered health practitioners who are suitably trained and qualified are able to use protected titles. The law allows for penalties for falsely using protected titles or holding out to be a registered practitioner. The maximum penalty which a court may impose is \$30,000 (in the case of an individual) or \$60,000 (in the case of a body corporate).

The court ordered Mr Donegan to pay a fine of \$10,000 and costs to AHPRA in the amount of \$1,085. The court refused an application by Mr Donegan for spent conviction* orders (**a spent conviction is a criminal conviction that is treated as though a formal conviction was not recorded by a court*).

National Scheme news

Scheduled Medicines Expert Committee appointed

Late last year the Australian Health Workforce Ministerial Council (Ministerial Council) endorsed the AHMAC Guidance for National Boards: Applications to the Ministerial Council for approval of endorsements in relation to scheduled medicines under section 14 of the National Law (the Guidance).

The Guidance is published on the AHPRA website under [Ministerial directives and communiques](#). It provides information for National Boards about the process for, and content of, an application to the Ministerial Council for approval of endorsement for scheduled medicines for a health profession under section 14 of the National Law.

Consistent with the Guidance, AHPRA has established a Scheduled Medicines Expert Committee (Expert Committee) whose role is to advise National Boards on the use of scheduled medicines generally, and on matters relevant to a National Board's proposal for a new scheduled medicines endorsement or an amendment to an existing scheduled medicines endorsement.

Following a call for applications, AHPRA is pleased to announce the following appointments to the Expert Committee:

- Professor Anne Tonkin, Chair
- Ms Vanessa Brotto, core member
- Dr Susan Hunt, core member
- Professor Lisa Nissen, core member
- Ms Sarah Spagnardi, core member

The Expert Committee is expected to hold its inaugural meeting later this year. Information about the Expert Committee, including the terms of reference, will be published on the AHPRA website shortly.

Keep in touch with the Board

- Visit the [Pharmacy Board 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 [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.

