



Pharmacy Council of New South Wales

Protecting the public
Regulating pharmacists and pharmacies

Annual Report 2016-17



President's Message



Protecting the public
Regulating pharmacists and pharmacies

Welcome to the Pharmacy Council of New South Wales section of the annual report.

The past twelve months have been busy for the Pharmacy Council. This is an opportunity to provide some insight into the past year and the year ahead.

Since the inception of national registration in 2010, the number of complaints and notifications made against pharmacists in NSW has risen year on year. This year has been no exception to that trend and is in line with the national trend also. It is difficult to know why this is the case but it is something that both the Council and practitioners must consider. Often the way a consumer complaint is handled initially can be the difference between a notification being made and the problem being resolved. I would urge pharmacy owners, pharmacy managers and all pharmacists to revisit your procedures for complaint management and incident reporting. You may like to involve your professional indemnity insurer in this review.

In the last year several complaints have related to supply of large quantities of Schedule 8 medications at short intervals to patients on forged prescriptions. Again this is an area that could be reviewed on a regular basis by all pharmacists to minimise the possibility of this occurring in your workplace.

The number of pharmacies providing a complex compounding service continues to grow. In the past year the Council, in an effort to inform itself of the current trends and issues, has engaged with suppliers, training organisations and other regulators to work towards providing guidance to practitioners in this area. We have also formed a working group that is working on providing guidelines for premises undertaking compounding. We would be happy to receive any feedback with regard to this initiative whether that is positive or negative.

We have continued our efforts to improve stakeholder engagement which has involved staff and Council members attending conferences, education sessions, university presentations and Intern training programmes as well as meetings with other regulators and professional associations. We aim to increase this level of interaction in the coming year.

I would like to thank my fellow Council members for their dedication, input and support over the last year. To the growing group of non-members who act as mentors, auditors, performance reviewers and panel members, on behalf of all Council members, I thank you for your efforts and experience in assisting Council do its job.

Finally, none of this could have been achieved without all our dedicated support staff and Health Professional Councils Authority (HPCA) executives. It has been a difficult year with staff turnover and upcoming organisational changes; to those that have moved on we thank you for your input, and to those that remain we are deeply appreciative of your dedication and commitment to making our role easier.

A handwritten signature in black ink, appearing to read 'S. Ludington', is written over a light blue horizontal line.

Stuart Ludington

President

Pharmacy Council of New South Wales

Regulation of
Pharmacists in 2016/17

Summary overview



272

**New complaints
received during the
year related to**

Conduct - 64
Performance - 195
Health - 13

14 complaints were mandatory
notifications



9,270

**Registered
Pharmacists in NSW**

1.1% more than the previous year
30.5% of Pharmacists in Australia
2.7% of Pharmacists in NSW had
complaints made about them -
250 practitioners



414

Complaints managed

142 open at start of year
272 received during the year
59 immediate actions including reviews
132 assessments and hearings concluded
217 closed during the year
197 open at year end
76 active monitoring at year end



225

Outcomes for closed complaints*

87 no further action
66 discontinued
29 conditions on registration
17 no jurisdiction or referred
13 counselling
6 caution or reprimand
2 registration cancelled
2 registration surrendered
2 withdrawn
1 change to non-practising

* A complaint may have more
than one outcome

Emerging issues and trends

Compounding

During the previous year complex compounding in community pharmacies emerged as an issue with a number of complaints dealt with by the Council involving a lack of knowledge and adherence to legislative requirements and the Pharmacy Board of Australia's compounding guidelines.

In response to growing concerns around the practice of compounding, the Pharmacy Council established a Compounding Working Group, commissioned targeted research and held a number of joint meetings with its regulatory stakeholders to gain a broader understanding of the current compounding environment. Work will continue in the next reporting period to formulate strategies and develop resources to assist the Council in responding to identified areas of need related to compounding.

Council Communications

The Pharmacy Council website is the Council's primary communications tool to engage with pharmacists and the wider community. The Council's website is being redeveloped and updated and is expected to provide a modern, more interactive and user-friendly platform for the public, practitioners and other visitors.

The website redevelopment involved stakeholder and community consultation that included workshops, focus groups and user testing. The new website will include easy access to the Council's new online complaint form, with detailed information about the complaint process and will make it easier for visitors to access information about the Council, including policies and publications.

The new website is expected to be launched in August 2017.

The Pharmacy Council regularly distributes electronic newsletters to pharmacists with a principal place of practice in NSW, owners of NSW pharmacies and interested stakeholders.

Council Members

Ten members sit on the Pharmacy Council as prescribed by section 41E of the National Law.

Five members are nominated by the Minister for Health and appointed by the Governor.

Five members are local pharmacists elected by local pharmacists.

Registered pharmacist practitioner members nominated by the Minister and appointed by the Governor:

- Ms Terry Anne Maunsell BPharm, FSHP
- Ms Joyce Cooper BSc(Pharmacy), GradDipClinPharm, MRPharmS(GB), MSHP

Legal member:

- Ms Penny Ho LLB (Hons), LLM

Part 2: Reports from Health Professional Councils

Community members:

- Ms Marilyn Starr
- Ms Carolyn Burlew BA, MPubAd, FAICD

Elected local pharmacist members:

- Mr Stuart Ludington BPharm, MPS
- Mr Adrian Wei-Chun Lee BPharm, MCom, MAICD
- Mr Michael (Mike) Anderson BPharm, AACP
- Mrs Anne Reynolds BPharm, MPS
- Mr Paul Sinclair BPharm, MAICD, AACP

Mr Stuart Ludington is appointed by the Governor as President of the Pharmacy Council.

Mr Adrian Wei-Chun Lee is appointed by the Governor as Deputy President of the Pharmacy Council.

Executive Officer

Ms Nina Beeston is the Executive Officer for the Pharmacy Council. The Executive Officer leads a team of eleven who work directly with the Council.

All staff working both directly and indirectly with the Council are employed by the HPCA as an executive agency of the Ministry of Health. Councils cannot employ staff under the National Law.

Council Meeting Attendance

The Pharmacy Council met 13 times during the year.

Member attendance at Council meetings, eligibility to attend and length of office

Member	Meetings Attended	Meetings Eligible to Attend	Length of Office*
Mr Stuart Ludington – President	13	13	1 April 2016 - 31 March 2019
Mr Adrian Wei-Chun Lee – Deputy President	12	13	1 April 2016 - 31 March 2019
Mr Michael (Mike) Anderson	12	13	1 April 2016 - 31 March 2019
Ms Carolyn Burlew	12	13	4 July 2012 - 30 June 2018
Ms Joyce Cooper	12	13	1 July 2015 - 30 June 2018
Ms Penny Ho	12	13	1 July 2015 - 30 June 2018
Ms Terry Anne Maunsell	12	13	25 March 2009 - 31 March 2018
Mrs Anne Reynolds	13	13	1 April 2016 - 31 March 2019
Mr Paul Sinclair	11	13	1 April 2016 - 31 March 2019
Ms Marilyn Starr	12	13	4 July 2012 - 30 June 2018

* Council members are appointed for a term up to three years and may be reappointed up to a maximum of nine years.

Regulatory Committees and Panels

Part 8 of the National Law prescribes the committees and panels that support the Council in undertaking its regulatory activities.

Regulatory committees and panels include:

- Assessment Committee
- Impaired Registrants Panel
- Performance Review Panel

The Pharmacy Council appointed one Impaired Registrants Panel and one Performance Review Panel during the year.

Impaired Registrants Panel

The Impaired Registrants Panel (IRP) deals with matters where a registered health practitioner has a physical or mental impairment that affects, or is likely to affect their capacity to practise safely.

An IRP consists of two or three people who may or may not be Council members. At least one member must be registered in the same profession as the practitioner who is subject of the complaint and at least one panel member must be a medical practitioner. Panel members are selected from a pool of people who have undergone probity checks and are experienced in working with practitioners who have health problems.

Performance Review Panel

The Performance Review Panel (PRP) may review matters where unsatisfactory professional practice is indicated. The PRP examines evidence to establish whether a practitioner is performing to a standard reasonably expected of practitioner with their level of training and experience.

A PRP consists of three people who may or may not be Council members. At least two panel members must be registered in the same profession as the practitioner who is subject of the complaint and one member must not be a health practitioner. Panel members are required to undergo probity checks.

Pharmacy Council Panels

Impaired Registrants Panel	Performance Review Panel
Non Council Members Dr Alison Reid Mrs Elizabeth Frost	Non Council Members Ms Rosemary Kusuma - Chair Ms Zaheeda Patel Mr Jonathan Chen

Council Committees

Councils may establish committees to assist with Council functions. Committee members are not necessarily Council members.

The Pharmacy Council reappointed five of its committees at the beginning of the year.

Notifications Committee

The Notifications Committee reviews all new complaints in consultation with the Health Care Complaints Commission (HCCC). Complaints referred to the Council for management following consultation with the HCCC are dealt with according to the provisions of the National Law.

Committee meetings are held on the third Thursday of each month.

Finance Committee

The Finance Committee provides oversight and management of Information and Communications Technology (ICT), strategic plans and financial matters. The Committee also advises and makes recommendations to the Council in relation to the following:

- Council's budget, budget projections and financial reports
- ICT matters
- HPCA Strategic Plan
- Service Level Agreement between the HPCA and the Council

The Committee met on 11 occasions.

Ownership Committee

The Ownership Committee considers complex matters related to pharmacy ownership and makes recommendations to the Council about:

- Policy and procedural matters relating to pharmacy ownership
- Monitoring of incomplete ownership applications
- Action that may be taken in response to breaches of the Law of a serious nature relating to ownership

The Committee met on 11 occasions.

Communications Committee

The role of the Communications Committee is to:

- Publish and distribute information concerning the Health Practitioner Regulation National Law (NSW) and the Regulation to pharmacists, consumers and other interested persons
- Publish reports, information and advice to pharmacists, consumers and other stakeholders concerning health, performance and conduct issues related to pharmacists and issues related to the ownership of pharmacy businesses
- Review, assess and determine the content of the Council's website and newsletter
- Review the HPCA Communications Framework and the HPCA and Councils' Communications Plan and make recommendations to the Council.

The Committee met on 4 occasions.

Education and Research Committee

Section 41S of the National Law allows the Council to establish an Education and Research Account to provide funds for education and research purposes relevant to its regulatory functions and for meeting any associated administrative costs.

The Education and Research Committee met on one occasion to consider and make recommendations to the Council on applications for funding.

Pharmacy Council Committee Membership

Notifications Committee	Finance Committee	Ownership Committee
Chair Ms Joyce Cooper	Chair Ms Carolyn Burlew	Chair Mr Mike Anderson
Council Members Ms Penny Ho Mr Stuart Ludington Mrs Anne Reynolds Ms Marilyn Starr	Council Members Mr Adrian Lee Mr Stuart Ludington Ms Terry Maunsell Mr Paul Sinclair	Council Members Ms Joyce Cooper Mr Stuart Ludington Mr Paul Sinclair
		Non Council Members Ms Maria Watts

Communications Committee	Education and Research Committee
Chair Mrs Anne Reynolds	Chair Ms Terry Maunsell
Council Members Mr Mike Anderson Mr Adrian Lee Mr Stuart Ludington Ms Marilyn Starr	Council Members Mr Mike Anderson Ms Joyce Cooper Ms Penny Ho Mr Stuart Ludington

Compounding Working Group

The Compounding Working Group was established in October 2016 in response to growing concerns around the practice of compounding. The purpose of the Working Group is to gain a broader understanding of the current compounding environment, to formulate strategies and to develop resources to assist the Council in responding to identified areas of need related to compounding. The Group met on 8 occasions.

Compounding Working Party

Chair

Mr Paul Sinclair

Council Members

Ms Penny Ho

Mr Mike Anderson

Ms Terry Maunsell

Ms Joyce Cooper

Meetings and Events

The Pharmacy Council was represented at the following meetings and events during the year.

Pharmacy Council representation at meetings and events

Name of Meeting / Event	Attended By	Attendee Role
Meeting on prescribing and compounding of peptides – HCCC/PRU/Medical Council	Mr Stuart Ludington Mr Adrian Lee	Participant Participant
NRAS Stakeholder consultation forum	Mr Stuart Ludington Ms Katharina Nicholson (HPCA)	Participant Participant
Pharmacy Premises Registering Authorities of Australia (PPRAA) meetings	Mr Adrian Lee Ms Maria Watts (HPCA)	Member Member

The Council also met with the Pharmacy Board of Australia Notifications Committee and representatives of the Pharmaceutical Regulatory Unit, NSW Ministry of Health.

Stakeholder Input

During the year the Pharmacy Council provided submissions in response to a number of calls for comment.

Pharmacy Council submissions

Name of agency	Consultation
Commonwealth Department of Health	Review of Pharmacy Remuneration and Regulation
Pharmaceutical Society of Australia	Code of Ethics for Pharmacists
Pharmaceutical Society of Australia	Professional Practice Standards Consultation 2017
Pharmaceutical Society of Australia	Professional Practice Standards Consultation - Compounding 2017
Pharmaceutical Society of Australia	Dose Administration Aides Guidelines
NSW Ministry of Health	Consultation on possible amendments to the National Law - unregistered practitioners

Education and Research

The Pharmacy Council maintains an Education and Research account to fund activities that assist better understanding of conduct, performance and health issues amongst practitioners and students and management of these issues.

The Pharmacy Council offers two types of grants:

- Research and Project Grants to a maximum of \$10,000
- Development and Education Grants to a maximum of \$2,500.

Education and Research account expenditure this year totalled \$15,861 for the following:

- Award to Branko Radjkovic to part fund his working visit to the pharmacy department of the Johannes Gutenberg University Teaching Hospital, Germany to enable professional exchange and cooperation in the field of clinical pharmacy, with emphasis on the extemporaneous preparation of medicines, aseptic manufacturing and the preparation of cytotoxic medications. The above areas are emerging trends amongst complaints received by the Pharmacy Council.
- Final payments to The University of Sydney for 'Status of Current Teaching in Professional Ethics in Pharmacy and Development of Curriculum Resource'.
- Final payment to The University of Sydney for 'Enabling Pharmacists to Improve Care of People living with a Disability in NSW'.
- Payment to the University of Sydney for 'Community Pharmacists and People at Risk of Suicide: An Examination of Experiences, Attitudes and Stigma'.

Compounding of Medicines Research Project

In response to receiving an increasing number of complaints involving compounding within community pharmacies, the Pharmacy Council commissioned a body of research to assist it in its understanding of the extent of current compounding practice in New South Wales.

The University of Canberra was awarded \$10,000 for its project 'Investigation of the service of compounding medicines in New South Wales and comparison with other compounding services offered in Australia and overseas'. It is anticipated that the project will be completed by December 2017.

Overseas Travel

The Pharmacy Council did not incur any overseas travel costs during the year.

Remuneration

Council members received the following remuneration.

President	\$33,264 per annum
Deputy President	\$22,176 per annum
Council Members	\$11,088 per annum

Council members also receive sitting fees for conducting Council Inquiries, attending committee meetings and undertaking other regulatory activities if these are on a day other than the regular Council meeting.

Council members are reimbursed for expenses when travelling on official business at Council direction.

Panel and Tribunal members receive remuneration and reimbursement of expenses related to Council business.

Regulation of Pharmacy Businesses

The Pharmacy Council is responsible for the registration of pharmacies in NSW in addition to management of complaints about pharmacists.

As at 30 June 2017 there were 1,969 pharmacies registered in NSW.

Register of Pharmacies

Clause 14 of Schedule 5F of the National Law requires the Council to keep a Register of Pharmacies.

Changes to the Register of Pharmacies occur upon the approval of applications to the Council, satisfactory inspection of premises where required and payment of the relevant fee where applicable.

There were 446 changes to the Register of Pharmacies in 2016/17.

Change	Number
New Pharmacy	46
Pharmacy Relocation /Resizing	66
New Professional Services Room	3
Professional Services Room Relocation/Resizing	nil
Change of Pharmacy Ownership	182
Change of Pharmacy Name	115
Acquisition of a financial interest in a pharmacy business by acquiring shares in a Pharmacist's Body Corporate and / or appointment of new director(s)	15
Pharmacy Closure	19

Fees

On 1 July 2016, the Health Practitioner Regulation (New South Wales) Amendment (Pharmacy Fees) Regulation 2016 commenced operation. From this date the ability of the Pharmacy Council to set pharmacy ownership application fees and charges was removed. Under the Regulation, pharmacy fees are payable for approval of pharmacy premises and registration of holders of a financial interest in pharmacy businesses. All fees are prescribed by the Regulation.

Application forms are available on the Council's website www.pharmacycouncil.nsw.gov.au

Offences under Schedule 5F of the National Law

Schedule 5F of the National Law sets out provisions related to the holding of financial interests in pharmacy businesses and the responsibilities of pharmacy owners which, if contravened, may give rise to a Council initiated Local Court prosecution.

No Local Court prosecutions were conducted during the year.

Pharmacy Inspectors

Pharmacy inspectors have the state-wide function of conducting inspections and investigations to enforce compliance with the National Law and the Regulations. This includes inspection of existing, new and relocating pharmacies and investigation of complaints about pharmacists.

Pharmacy inspectors are appointed as authorised persons under section 164 of the National Law, with powers under section 164A to enter and inspect premises, to copy and/or seize records and to require persons to answer questions and also have responsibilities under the Poisons and Therapeutic Goods Act 1966 regarding safe handling of medications.

Pharmacy inspectors undertake the following activities.

Routine inspections

Pharmacies across NSW are routinely inspected every 18 months to ensure compliance with the requirements of the National Law and Regulations.

Application approval inspections

The approval by the Council of an application concerning the relocation of an existing pharmacy or the establishment of a new pharmacy business is subject to a satisfactory inspection to ensure compliance with the legislative requirements prior to commencing business on a new site.

Complaints inspections

The Council's Notifications Committee may request an inspection be conducted as part of its process of making inquiries into a complaint. During the year inspections were conducted after receiving the following types of complaints:

- Operating a pharmacy without a pharmacist in charge
- Dispensing error
- Physical condition of the pharmacy and storage of stock
- Inadequate record keeping
- Smoking/drinking alcohol on the premises.

The Notifications Committee considered the inspection reports in determining action to appropriately manage the complaints.

Drug destructions

Pharmacy inspectors are authorised by the NSW Ministry of Health Pharmaceutical Services to destroy and dispose of unusable Schedule 8 medication.

The Council was assisted by two pharmacy inspectors who undertook the following activities.

Activity	Number
Routine inspections	1,531
Inspections of relocated pharmacies and new pharmacy premises	95
Compliance/Complaint related inspections	14
Drug destructions	279

Financial Management

The Pharmacy Council's accounts performance was reported in the Financial Statement as follows.

Accounts Performance 2016/17	\$
Revenue	3,117,063
Operating expenditure	2,657,285
Gain / (loss) on disposal	-
Net result	459,778
Net cash reserves* (cash and cash equivalents minus current liabilities)	3,455,811

* Included in the cash reserves is an Education and Research bank account balance of \$10,194.

The Pharmacy Council's budget for the period 1 July 2017 to 30 June 2018 is as follows.

Budget 2017/18	\$
Revenue	2,896,647
Operating expenditure	4,325,304
Net result	-1,428,657

Full financial statements are presented in Part 3 of this report 'Financial Statements for NSW Health Professional Councils'.