AUSTRALIAN PHARMACY LAW AND PRACTICE

Laetitia Hattingh
John Low
Kim Forrester

2ND EDITION

sample proofs © Elsevier Australia
<table>
<thead>
<tr>
<th>CONTENTS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1    Legal concepts for health professionals</td>
<td>1</td>
</tr>
<tr>
<td>2    Pharmacy practice developments</td>
<td>23</td>
</tr>
<tr>
<td>3    Ethics and professional conduct</td>
<td>39</td>
</tr>
<tr>
<td>4    Practice standards and guidelines</td>
<td>61</td>
</tr>
<tr>
<td>5    National registration and accreditation</td>
<td>81</td>
</tr>
<tr>
<td>6    Pharmacy ownership</td>
<td>109</td>
</tr>
<tr>
<td>7    Investigation, discipline and legal proceedings</td>
<td>121</td>
</tr>
<tr>
<td>8    Medicare and the Pharmaceutical Benefits Scheme</td>
<td>159</td>
</tr>
<tr>
<td>9    Privacy, confidentiality and consent</td>
<td>181</td>
</tr>
<tr>
<td>10   Commonwealth medicine registration and regulation</td>
<td>207</td>
</tr>
<tr>
<td>11   State and territory medicines legislation</td>
<td>231</td>
</tr>
<tr>
<td>12   Occupational health and safety</td>
<td>269</td>
</tr>
</tbody>
</table>
FOREWORD

Having a clear understanding of the laws and standards that govern the practice of pharmacy in Australia is an essential prerequisite to ensuring the profession is practised in a competent and safe manner.

Knowledge is the key. Pharmacists entering the profession need to build a strong understanding of all the legal and professional guidelines that are in place to aid them in their pursuit of best practice.

*Australian Pharmacy Law and Practice* is a very worthwhile peer-reviewed publication that can only enhance and guide any pharmacist who wants to further their knowledge of the healthcare profession and ultimately serve to better educate not only themselves but also their colleagues, resulting in the highest standards being utilised in supporting and caring for the community at large.

As chairman of Pharmaceutical Defence Limited I commend this second edition of *Australian Pharmacy Law and Practice* to you.

Dean Schulze  
*National Chairman, Pharmaceutical Defence Limited*

The constantly evolving nature of pharmacy practice in Australia presents many challenges for practising pharmacists, not the least of which is staying up to date with the raft of legal, regulatory and policy developments that affect our everyday business and professional operations.

The Pharmaceutical Society of Australia is pleased to see Chapters 3 and 4 covering ethics and professional conduct, and practice standards and guidelines. Pharmacists have a responsibility and commitment to the profession to be competent, to practise at the highest standard and to ensure they serve the community of Australia in a manner that optimises the quality use of medicines and achieves positive health outcomes.

*Australian Pharmacy Law and Practice* therefore serves a critical need for every pharmacist in helping to ensure legal and regulatory compliance, as well as providing background, history and discussion of the law so that we can apply and critically evaluate the information in the best interests of our practice and our customers.

Grant Kardachi  
*National President, Pharmaceutical Society of Australia*

In the early 1980s when I was undertaking my undergraduate pharmacy degree, our lecturers were fond of telling us that, as pharmacists, we would be the ‘custodians of drugs’. While that remains true of pharmacists nearly 30 years later, in the second decade of the 21st century, pharmacists are so much more than that. As leaders in medicines management, pharmacists now play an integral part in the multidisciplinary team, helping our patients to get the most out of their medicines.

Legal and ethical practice has expanded from needing to obey a series of didactic rules laid down in the legislation, to a set of behaviours that reinforce the place of trust that the public has placed in our profession. How we interact with our patients, the community and our colleagues, both within and outside of our own profession,
determines how successful we are as practitioners and the extent to which our profession can continue to grow. The matter of trust is integral to ethical and legal practice. That balance between security of drugs and access to them determines how well we can manage the custodianship. We can never lock up medicines so securely as to prevent every illegal activity, neither can we make items prone to abuse so accessible that we invite inappropriate access. It’s a fine balance. We must trust that most people will do the right thing most of the time while setting up systems that can detect or deter aberrant behaviour. Vigilance is key. So too is ethical behaviour in the way we deal with our healthcare colleagues and our patients and the community. Pharmacists regularly poll in the top three most trusted professionals. To keep that level of trust among our patients and colleagues we must behave in an exemplary manner and as a profession deal with unethical behaviours in an expedited and consistent manner.

In the 21st century, practising in a legal and ethical manner involves pharmacists recognising that they must be competent in practising to their scope of practice and striving for excellence in their practice, in whatever setting they choose. The interests of the patient must always override the commercial interest and the self-interest that will inevitably lead to unethical behaviour. This revised edition of *Australian Pharmacy Law and Practice* provides students and practitioners with the tools they will need to develop and maintain an ethically sound practice. For undergraduate students, I sincerely believe that if you follow the guidance in this text, and follow the codes of ethics of your chosen professional organisation, then you will lead a challenging but rewarding professional life. Good luck!

*Sue Kirsa*

*National President, The Society of Hospital Pharmacists of Australia*
PREFACE

This book seeks to provide an introduction to contemporary pharmacy practice in Australia in the context of the various laws, policies and standards that govern the profession. The authors believe it will provide an overview not only to pharmacy undergraduates, pharmacy interns and pharmacists in all branches of the profession but also to overseas pharmacists seeking to register and practise in Australia or otherwise desiring knowledge and guidance of pharmacy practice. The past two decades have seen a dramatic expansion in the law and practice content of pharmacy courses in Australia. This growing demand for including legal content into the curriculum of pharmacy courses is in response to the demand by pharmacists for knowledge of legal principles and the legislative provisions underpinning their area of practice.

The authors come from a background of community, hospital and consultant pharmacy, academia, nursing and the law, and bring a wide range of clinical and professional experience. The practice experience of the authors includes medication review, oncology, critical care, medical/surgical nursing and coronary care. The authors also bring extensive experience in pharmacy regulation at both the state and the national level. The authors currently teach students in a variety of health disciplines and have used that experience to inform themselves as to the needs of students. While the book is not intended to detail every aspect of Australian pharmacy the authors believe it provides a comprehensive starting point for practitioners to identify relevant information sources and principles to further advance their knowledge.

The book comprises 12 chapters covering aspects of medicine regulation and pharmacy practice. The authors have intended that each of the chapters stand alone to avoid the reader having to continually refer to other areas of the text to follow a particular argument. Also note that while the authors have tended to use the term ‘medicine’ rather than ‘drug’ when referring to a chemical intended for human or animal therapeutic use, the term ‘drug’ does appear in the text in those circumstances where it is relevant to legislation or in other instances where the authors consider it more appropriate.

Chapter 1 gives an overview of legal concepts for health professionals. Chapters 2–4 cover aspects of pharmacy practice, including its development and evolution, ethics and professional conduct, and the importance of practice standards and guidelines. Chapters 5–7 consider the impact of legislation specific to pharmacy practice, covering the registration of pharmacists (including the proposed national registration scheme) and pharmacy ownership, as well as complaint handling including investigation, discipline and legal proceedings. Chapter 8 addresses Medicare and the Pharmaceutical Benefits Scheme, outlining the structure of the Australian healthcare system in regard to pharmaceuticals and identifying some limitations of the scheme. This leads into Chapter 9, which discusses the legal and professional obligations regarding privacy, confidentiality and consent. Chapters 10 and 11 consider medicine regulation from both the Commonwealth and the state and territory perspectives. Chapter 12 concludes the book by considering occupational
health and safety issues in the context of pharmacy practice and the preparation of medicines of a hazardous nature.

The task of writing this book was not made any easier by the federal system of government in Australia or by the dynamic nature of pharmacy regulation. Each government in the federal system (six states, two territories and the federal government) has law-making functions, with the Australian Constitution giving the federal government certain enumerated powers. While there has been significant work undertaken by legislators in the past two decades to harmonise state-based legislation there still is a lack of consistency between the states where some legislation is concerned.

The authors were drawn to the subject firstly on the basis of need, where the importance of considering pharmacy practice in all its facets in the context of the legal framework was seen as paramount, and second by the lack of any similar publication that specifically considers the Australian situation.

Finally we wish to acknowledge and thank all those who have provided assistance. The authors wish to thank Melinda McEvoy and Amanda Simons from Elsevier. The book is dedicated to Marie Low, Will Hattingh and Julian Pearce. While the legislation is as current as possible when going to press, no statement of the law should be relied upon without verification.

Laetitia Hattingh
John Low
Kim Forrester
2013
CHAPTER 7:
INVESTIGATION, DISCIPLINE AND LEGAL PROCEEDINGS

Learning objectives
Upon completion of this chapter you should be able to:

- explain the purpose of professional disciplinary processes
- understand the mandatory notification obligations and the criteria for voluntary notification
- define unsatisfactory professional performance, unprofessional conduct, professional misconduct and unsatisfactory professional conduct
- describe basic principles involved in pharmacy disciplinary processes in your jurisdiction
- provide examples of disciplinary cases and outcomes
- list the elements of professional negligence
- explain processes to follow after a mistake.

Competency standards (2010)
1.1 Practise legally
1.2 Practise to accepted standards
1.4 Manage quality and safety
3.4 Manage quality service delivery
INTRODUCTION

Mistakes arising in the delivery of pharmacy services have the potential for serious consequences. When a customer alleges that they have suffered an injury as the result of an act or omission by a pharmacist, there are a number of options available to them to pursue the matter. These include:

- accessing the internal complaints mechanisms of the institution or the private provider
- lodging a complaint (notification) with the Pharmacy Board of Australia (PBA) through the Australian Health Practitioner Regulation Agency (AHPRA)
- lodging a complaint with the independent statutory complaints unit or commission established in each state or territory
- initiating action through the adversarial court system, for example, a civil claim for damages.

More than one of these processes can be pursued simultaneously. To gain some understanding of the possible outcomes where complaints are lodged against pharmacists or legal actions initiated, the framework of both the PBA’s investigation and disciplinary powers (and the various tribunals in the states and territories) and outcomes of civil litigation through the courts should be understood.

It is also important that the public has confidence in the investigatory, disciplinary and legal processes, and that these are consistent and transparent with outcomes that reflect the gravity and nature of the matter. This chapter will focus on the processes in place for investigating and disciplining pharmacists, as well as providing a summary of legal actions that may flow from complaints made about a pharmacist and/or their pharmacy practice.

INVESTIGATIONS AND DISCIPLINE

In addition to the registration process (see Ch 5), the Health Practitioner Regulation National Law Act 2009 empowers the PBA, in collaboration with AHPRA, to assume responsibility for investigating and disciplining pharmacists. This includes the authority to receive complaints, investigate allegations of misconduct by pharmacists and take appropriate disciplinary action where necessary. In addition to the national board’s disciplinary processes, there are the health complaints commissions in each state and territory[^1] that can also handle service complaints from the public. These commissions were established as part of a general move towards recognising greater consumer rights.[^2] Complaints are managed through legislative arrangements and/or memorandums of understanding between the relevant commissions and AHPRA (on behalf of a national board), being dealt with by either body depending on the nature and seriousness of the complaint.

It is important to note that in New South Wales (NSW) complaints about the performance, conduct or health of regulated practitioners are managed under a co-regulatory system. Section 6 of the Health Practitioner Regulation (Adoption of National Law) Act 2009 (NSW) confirms:

... that this jurisdiction is not participating in the health, performance and conduct processes provided by ... the Health Practitioner Regulation National Law.
Under the NSW system notifications and complaints made about regulated NSW health practitioners received by AHPRA are forwarded to the NSW Health Care Complaints Commission and the individual health professional councils to be dealt with. The PBA is not involved in notifications or complaints about performance, conduct or the health of a pharmacist practising in NSW.

The following is a brief outline of the provisions of the National Law Act that address complaints, investigations and discipline. The chapter will also address the NSW processes in relation to complaints, investigation and discipline in that jurisdiction.

**The National Registration and Accreditation Scheme**

The National Law Act sets out the obligations and processes for a notification in relation to complaints about regulated practitioners, the investigation of complaints and the potential outcomes. The legislation also defines the grounds for a notification to AHPRA, and the conduct or behaviour that will determine whether a complaint will generate disciplinary proceedings or a response that addresses the health of the individual practitioner.

**Notification of a complaint**

The role of the PBA and AHPRA, in responding to complaints about the performance, conduct or health of a pharmacist, is consistent with the objectives of the National Law Act. That is, to protect the public (section 3(2)(a)) and facilitate public access to health services provided by health practitioners in accordance with the public interest (section 3(2)(e)). These objectives are addressed through the notification processes whereby AHPRA (on behalf of the PBA) is notified of concerns about the professional performance, conduct or health of a pharmacist. Notifications to the PBA are dealt with through a formal delegation to a notification committee. This is different from the process for notifications in relation to medicine, nursing, midwifery and physiotherapy where notifications are dealt with by state- or territory-based boards. Notifications to AHPRA can be made in compliance with the mandatory obligations imposed on registered health practitioners, employers and education providers, or as voluntary notifications.

The National Law Act imposes a **mandatory obligation** to notify AHPRA as soon as practicable if, in the course of practising their profession, a pharmacist forms the reasonable belief that another health practitioner (not only another pharmacist) has behaved in a way that constitutes **notifiable conduct** or that a student has an **impairment** that, in the course of the student undertaking clinical training, may place the public at substantial risk of harm (section 141). The mandatory obligation imposed on employers and education providers are similarly worded. It is important to note that, with the exception of Western Australia, the mandatory reporting obligation applies when the notifying practitioner is also the treating practitioner. The obligation imposed under section 140 of the National Law Act defines **notifiable conduct** in relation to registered health practitioners to mean the practitioner has:

(a) **practised the practitioner’s profession while intoxicated by alcohol or drugs**; or
(b) engaged in sexual misconduct in connection with the practice of the practitioner’s profession; or
(c) placed the public at risk of substantial harm in the practitioner’s practice of the profession because the practitioner has an impairment; or
(d) placed the public at risk of harm because the practitioner has practised the profession in a way that constitutes a significant departure from accepted professional standards.

Impairment is defined under section 5 to mean ‘that the person has a physical or mental impairment, disability, condition or disorder (including substance abuse or dependence) that detrimentally affects or is likely to affect:

(a) for a registered health practitioner ... the person’s capacity to practise the profession; or
(b) for a student, the student’s capacity to undertake clinical training ...’

The National Law Act requires that the registered practitioner who reports the notifiable conduct must have formed a ‘reasonable belief’. The meaning of this term is set out in the PBA Guidelines for mandatory notification as:

... a stronger level of knowledge than mere suspicion. Generally it would involve direct knowledge or observation of the behavior which gives rise to the notification, or, in the case of an employer, it could also involve a report from a reliable source or sources. Mere speculation, rumours, gossip or innuendo are not enough to form a reasonable belief.\textsuperscript{[5]}

Exceptions to the formation of a ‘reasonable belief’ exist (section 141(4)) where a pharmacist acquires knowledge of the notifiable conduct or impairment through: disclosure as part of legal proceedings; preparing or providing legal advice; providing legal advice arising from an insurance policy claim; and exercising a function as a member of a quality assurance committee, council or other approved or authorised body under an Act that prohibits disclosure or if the practitioner knows or reasonably believes AHPRA has already been notified.

Regulated health practitioners in Western Australia are not required to lodge a mandatory notification about their patients or clients (who are also regulated health practitioners or students).\textsuperscript{[6]} However, the treating health practitioner may make a voluntary notification or encourage the patient or client to self-report.

The National Law Act also provides grounds for voluntary notification (sections 144 and 145) when:
- the conduct of the practitioner is, or may be, of a lesser standard than that which might be reasonably expected by the public or the practitioner’s peers
- the knowledge, skill or judgment possessed or care exercised is, or may be, below the standard reasonably expected
- the practitioner is not, or may not be, a suitable person to hold registration
- the practitioner has, or may have, an impairment
- the practitioner has, or may have, contravened the Act
- the practitioner has, or may have, contravened a condition of their registration or an undertaking they gave to the national board
- the practitioner’s registration was, or may have been, improperly obtained.

In relation to a pharmacy student, a voluntary notification may be made to AHPRA on the grounds that the student: has been charged with an offence; has been convicted and found guilty of an offence that is punishable by 12 months imprisonment or more; has or may have an impairment; or has or may have...
contravened a condition of their registration or an undertaking he or she gave to the national board.

The *Australian Health Practitioner Regulation Agency – Annual Report 2010–11* confirms that the ‘majority of reports made to AHPRA are voluntary. Typically, notifications are made by patients or their families, other health practitioners, employers and health complaints entities in each state or territory.’ Of the total 8139 notifications (1.3 per cent of the total 530,115 practitioners registered in Australia under the National Registration and Accreditation Scheme) received by AHPRA about regulated practitioners in 2010–11, 419 were in relation to pharmacists. The highest number of notifications received was in relation to medical practitioners (4122 notifications) and the smallest number related to osteopaths (19 notifications).

Section 237 of the National Law Act protects registered practitioners, employers and education providers who make a notification or provide information in good faith under the Act. The protection extends to civil, criminal and administrative liability including liability arising from actions in defamation. The provisions confirm that making a notification or giving information will not constitute a breach of professional ethics or etiquette or a departure from accepted standards of professional conduct.

If a registered practitioner fails to notify AHPRA of the notifiable conduct of another registered practitioner or a student’s impairment under the mandatory notification obligations this will not, under the Act, constitute an offence. However, the behaviour of the practitioner in breaching the legislative mandatory obligation to lodge a notification may itself provide the grounds for an action against that practitioner.

**Process**

On receipt of a notification AHPRA conducts a preliminary assessment to determine if the notification relates to a registered practitioner, concerns an issue that provides the grounds for a notification and whether the notification could also be made to a health complaints entity in the relevant state or territory. Where a notification is made about a regulated pharmacist both the PBA and the health complaints entity in the particular jurisdiction are empowered to share the notification. A memorandum of understanding between AHPRA and the respective health complaint entities in each state and territory identifies their roles and responsibilities in relation to a response to a notification.

In circumstances in which the notification indicates the pharmacist’s (or pharmacy student’s) conduct or impairment poses a serious risk to the public’s health and safety, the PBA may immediately (Immediate Action Committee) take action to limit the practitioner’s or student’s registration. This may include suspension, imposing conditions, accepting an undertaking or surrendering a practitioner’s or student’s registration. The PBA must give a registered health practitioner or student notice of the proposed action and the opportunity to make a submission to the board addressing the allegations contained in the notification.

Where the notification does not raise immediate concerns for the health and safety of the public there are a number of responses the PBA may decide to take including:

- **Take no further action** if the board ‘believes the notification is frivolous, vexatious, misconceived or lacking in substance ... it is not practicable for the board to investigate or deal with the notification ... given the amount of time...’
that has elapsed ... the person to whom the notification relates has not been, or is no longer, registered and it is not in the public interest to investigate ... the subject matter of the notification has already been dealt with adequately ... the subject matter of the notification is being dealt with, or has already been dealt with, adequately ... 

- **Undertake an investigation** into the practises, conduct or impairment that form the basis for the notification. As a general principle the practitioner or student would be notified by the board that an investigation had been initiated unless the board ‘believes that giving notice may seriously prejudice the investigation, or may place someone’s health or safety at risk or may place someone at risk of harassment or intimidation’.

- **Require the practitioner to undergo a health assessment** if the board believes the practitioner may have an impairment. If the board forms the view that the practitioner’s health is impaired the board may caution the practitioner and/or accept an undertaking and/or impose a condition on the practitioner’s registration.

- **Require the practitioner to undergo a performance assessment** if the board believes the practitioner practised in a way that is, or may be, unsatisfactory. If the board forms the view that the conduct or practice was unsatisfactory the board may caution the practitioner and/or accept an undertaking and/or impose a condition on the practitioner’s registration.

- **Refer the notification to another entity** such as the healthcare complaints body in the particular state or territory.

After receiving a notification and/or conducting an investigation, health or performance assessment the PBA may:

- make a decision to take no further action
- issue a caution
- accept an undertaking or impose a condition on the practitioner or student’s registration
- refer the matter to a health panel, performance and professional standards panel, or
- refer the matter to a ‘responsible’ state or territory tribunal.[11]

**REFERRAL OF A MATTER TO A RESPONSIBLE TRIBUNAL**

The PBA must refer a matter about a pharmacist or pharmacy student to a responsible tribunal under section 193(1) of the National Law Act if:

(a) ... the Board reasonably believes, based on the notification or for any other reason—

(i) the practitioner has behaved in a way that constitutes professional misconduct; or

(ii) the practitioner’s registration was improperly obtained because the practitioner or someone else gave the Board information or a document that was false or misleading ...

(c) a panel established by the Board requires the Board to refer the matter to a responsible tribunal ...

The ‘responsible tribunal’ for the hearing of a matter about a registered health practitioner will be in the state or territory in which the conduct occurred or, if the conduct occurred in a number of states or territories, in the state or territory that is the principal place of residence of the registered practitioner.[12]
The National Law Act prescribes the range of decisions that a tribunal may reach after hearing a matter about a registered health practitioner. The tribunal may find:

(a) the practitioner has no case to answer and no further action is to be taken in relation to the matter; or

(b) one or more of the following—

(i) the practitioner has behaved in a way that constitutes unsatisfactory professional performance;
(ii) the practitioner has behaved in a way that constitutes unprofessional conduct;
(iii) the practitioner has behaved in a way that constitutes professional misconduct;
(iv) the practitioner has an impairment;
(v) the practitioner’s registration was improperly obtained because the practitioner or someone else gave the National Board that registered the practitioner information or a document that was false or misleading in a material particular.

The terms unsatisfactory professional performance, unprofessional conduct and professional misconduct are defined by the National Law Act to mean:

- **unsatisfactory professional performance**, of a registered health practitioner, means the knowledge, skill or judgment possessed, or care exercised by, the practitioner in the practice of the health profession in which the practitioner is registered is below the standards reasonably expected of a health practitioner of an equivalent level of training or experience.

- **unprofessional conduct**, of a registered health practitioner, means professional conduct that is of a lesser standard than that which might reasonably be expected of the health practitioner by the public or the practitioner’s professional peers, and includes:
  (a) a contravention by the practitioner of this Law ...
  a contravention by the practitioner of—
    (i) a condition to which the practitioner’s registration was subject; or
    (ii) an undertaking given by the practitioner to the National Board ...
  (c) the conviction of the practitioner for a offence under another Act, the nature of which may affect the practitioner’s suitability to continue to practise the profession ...
  (d) providing a person with health services of a kind that are excessive, unnecessary or otherwise not reasonably required ...
  (e) influencing, or attempting to influence, the conduct of another registered health practitioner in a way that may compromise patient care; and
  (f) accepting a benefit as an inducement, consideration or reward for referring another person to a health service provider or recommending another person use or consult with a health service provider; and
  (g) offering or giving another person a benefit, consideration or reward in return for the person referring another person to the practitioner or recommending to another person that the person use a health service provided by the practitioner; and
  (h) referring a person to, or recommending that a person use or consult, another health service provider, health service or health product if the practitioner has a pecuniary interest in giving that referral or recommendation, unless the practitioner discloses the nature of that interest to the person before or at the time of giving the referral or recommendation.
• **professional misconduct**, of a registered health practitioner, includes:
  (a) unprofessional conduct by the practitioner that amounts to conduct that is substantially below the standard reasonably expected of a registered health practitioner of an equivalent level of training or experience; and
  (b) more than one instance of unprofessional conduct that, when considered together, amounts to conduct that is substantially below the standard reasonably expected of a registered health practitioner of an equivalent level of training or experience; and
  (c) conduct of the practitioner, whether occurring in connection with the practice of the practitioner’s profession or not, that is inconsistent with the practitioner being a fit and proper person to hold registration in the profession.

When the tribunal finds, based on the evidence before it, that the practitioner has conducted themselves in a manner that constitutes unsatisfactory professional performance, unprofessional conduct, professional misconduct, has an impairment or has improperly obtained their registration through providing false or misleading materials, the tribunal may do any one or more of the following:[15]

- caution or reprimand the practitioner
- impose conditions on the practitioner’s registration with a determined period to be reviewed
- require the practitioner to pay a fine of not more than $30,000 to the national board
- suspend the practitioner’s registration for a specified time
- cancel the practitioner’s registration.

In relation to a student the tribunal may decide, after hearing the evidence, that the student has no case to answer and no further action is to be taken, or that the student has an impairment and conditions will be imposed or the student’s registration suspended.[16]

NEW SOUTH WALES

In NSW the disciplinary process for registered health practitioners is separate and distinct from that which applies in the other states and territories under the national scheme. Notification, investigation and disciplinary processes for pharmacists and pharmacy students in NSW are provided for under the following legislative framework:

- Health Practitioner Regulation (Adoption of National Law) Act
- Health Practitioner Regulation National Law (NSW) No 86a
- Health Practitioner Regulation (New South Wales) Regulation 2010
- Health Care Complaints Act 1993 (NSW).

A notification or complaint about a pharmacist or pharmacy student in NSW will be forwarded to the Pharmacy Council of New South Wales and/or the Health Care Complaints Commission (HCCC), established under the Health Care Complaints Act. Even though a notification may initially be made to AHPRA it will be forwarded to the NSW co-regulatory authorities for action. The Pharmacy Council is a statutory body established in 2010 to manage notifications (complaints) about the conduct, performance and/or health of pharmacy practitioners and pharmacy students. Though the council manages the regulation of pharmacy businesses in NSW it is not responsible for registering either the pharmacy practitioners or students.[17]
 Conduct, performance and health

Under the Health Practitioner Regulation National Law (NSW) No 86a ‘conduct’ matters include ‘unsatisfactory professional conduct’ and ‘professional misconduct’. These terms are defined as follows:[18]

- **Unsatisfactory professional conduct** of a registered health practitioner includes:
  
  (a) Conduct that demonstrates the knowledge, skill or judgment possessed, or care exercised by the practitioner in the practice of their profession is significantly below the standard reasonably expected of a practitioner of an equivalent level of training or experience.
  
  (b) A contravention by the practitioner of a provision of this Law or a regulation under this Law
  
  (c) A contravention by the practitioner of a condition to which the practitioner’s registration is subject; or an undertaking given to a National Board
  
  (d) A contravention by the practitioner of a decision or order made by a Committee or Tribunal in relation to the practitioner
  
  (e) A contravention by the practitioner of section 34A (4) of the Health Care Complaints Act 1993 (NSW) (this section relates to the failure by a practitioner to provide the HCCC with information, documents or evidence required for an investigation)
  
  (f) Accepting from a health service provider a benefit as inducement, consideration or reward for referring another person to the health service provider, recommending another person use any health service provided by the health service provider or consult with the health service provider in relation to a health matter
  
  (g) Accepting from a person who supplies a health product a benefit as inducement, consideration or reward for recommending that another person use the health product. This does not include accepting a benefit that is consistent with ordinary retail conduct
  
  (h) Offering or giving a person a benefit as inducement, consideration or reward for the person referring another person to the registered health practitioner or recommending to another person that they use a health service provided by the practitioner or consult the practitioner in relation to a health matter
  
  (i) Referring a person to, or recommending that a person use or consult another health service provider, health service or health product if the health practitioner has a pecuniary interest in giving the referral or recommendation, unless the practitioner discloses the nature of the interest to the person before or at the time of giving the referral or recommendation
  
  (j) Engaging in overservicing
  
  (k) Permitting an assistant employed by the practitioner who is not a registered health practitioner to attend, treat or perform operations on patients in respect of matters requiring professional discretion or skill
  
  (l) Any improper or unethical conduct relating to the practice or purported practice of the practitioner’s profession.

In addition to the matters described above, **unsatisfactory professional conduct** of a pharmacist also includes:[19]

- Practising pharmacy for remuneration at a pharmacy in the course of employment by, or in association with, a non-pharmacist
- The supply of drugs or other substances in circumstances where they are unnecessary, not reasonably required or excessive
C. failure of the pharmacist who owns or has a pecuniary interest in a pharmacy business to display at or near the main entrance of the business premises the owner’s name
D. failure to display the name of the pharmacist in charge adjacent to the area where dispensing is carried on in the pharmacy
E. failure of the pharmacist who owns or has a pecuniary interest in a pharmacy business to ensure that the drug price information displayed in the pharmacy does not contravene the Price Information Code of Practice (within the meaning of Schedule 5F)

- **Professional misconduct** of a registered health practitioner means: \(^{[20]}\)
  (a) unsatisfactory professional conduct of a sufficiently serious nature to justify suspension or cancellation of a practitioner’s registration; or
  (b) more than one instance of unsatisfactory professional conduct that, when the instances are considered together, amount to conduct of a sufficiently serious nature to justify suspension or cancellation of the practitioner’s registration.

The definitions under the National Law Act for ‘unprofessional conduct’ and ‘unsatisfactory professional performance’ are not applicable in NSW. \(^{[21]}\) The professional performance of a pharmacist or pharmacy student must be maintained at an appropriate standard and therefore a notification (complaint) based on performance is grounds for investigative and disciplinary action by the Pharmacy Council of New South Wales. Performance is defined to be unsatisfactory if it is below the standard reasonably expected of a pharmacist or pharmacy student of an equivalent level of training or experience. That is, the knowledge, skill or judgment they possess, or the care they exercise, is below that standard. When a notification is lodged in relation to performance the pharmacist or pharmacy student may be required to undergo a performance assessment. \(^{[22]}\)

Health matters are based on the pharmacist or pharmacy student having an impairment from which they suffer from a physical or mental disability, disorder or condition that detrimentally affects, or is likely to affect, their capacity to practise or undertake clinical training safely. When the Pharmacy Council of New South Wales receives a notification based on the health of a pharmacist or pharmacy student it is likely that the practitioner or student will be subject to a health assessment. \(^{[23]}\)

**Notification**

A notification may be lodged by patients, clients, their parents, guardians, family members, carers, other healthcare providers or employers. Consistent with the National Law Act there is a mandatory obligation imposed on practitioners, employers and education providers to report notifiable conduct in relation to a practitioner or student. The sections of the NSW legislation are the same as those in the National Law Act (see *Notification of a complaint* above) and impose a mandatory obligation to notify AHPRA as soon as practicable after forming a reasonable belief that the practitioner or student has engaged in notifiable conduct. There are protections from civil, criminal and administrative liability for notifiers who acted in good faith. A mandatory notification does not constitute a breach of professional etiquette or ethics, nor will it provide the grounds for a breach of acceptable standards of professional conduct or defamation. \(^{[24]}\)

**PROCESS**

On receipt of a notification the Pharmacy Council notifies, as soon as practicable, the HCCC and AHPRA as part of the cross-notification arrangement between these
authorities. The HCCC and Pharmacy Council will then undertake a preliminary assessment of the complaint for the purpose of planning a course of action that is most appropriate for the particular complaint. The Pharmacy Council, under section 145B of the Health Practitioner Regulation National Law (NSW) No 86a, has a number of options available in response to a complaint about a registered pharmacist or pharmacy student including:

- making enquiries as considered appropriate
- referring the complaint to the HCCC for investigation
- referring the complaint to the Pharmacy Tribunal or the Committee of the Council
- dealing with the complaint by inquiry at a meeting of the council
- referring the practitioner or student for a health assessment, to the Impairment Registrants Panel or for a performance assessment
- directing the practitioner or student to attend counselling
- referring the complaint to the HCCC for conciliation
- referring the complaint to another entity (including the PBA)
- deciding that no further action will be taken.

The registered practitioner or student is then provided with a copy of the complaint.

All serious complaints lodged in relation to a pharmacist or pharmacy student (those that, if substantiated provide grounds for suspension or cancellation of their registration) are referred by the Pharmacy Council or the HCCC to the Pharmacy Tribunal. The only exception arises when the Pharmacy Council or HCCC are of the opinion that the allegations made in the complaint relate 'solely or principally to:

(a) for a practitioner, the physical or mental capacity of the practitioner to practise the practitioner’s profession; or
(b) for a student, the physical or mental capacity of the student to undertake clinical training in the health profession in which the student is registered.' In this situation the complaint will be referred to a committee of the council or Impairment Registrants Panel.

The Pharmacy Council may refer a complaint to the Assessment Committee if the HCCC has decided not to undertake an investigation or, having investigated the complaint, decided not to refer the complaint to the Pharmacy Tribunal. This committee cannot accept complaints that allege the pharmacist is not of good character or has been convicted of, or is the subject of, criminal findings. The Assessment Committee has no power to impose a decision about a complaint. However, it may undertake an investigation, require the pharmacist to undergo skills testing and/or encourage the complainant and pharmacist to reach a settlement by consent. The committee may obtain medical, legal, financial and other advice that is deemed necessary in the exercise of its functions. The report from the Assessment Committee to the Pharmacy Council may include recommendations that the council deal with the complaint by: inquiry, as a complaint of unsatisfactory professional conduct; advising that the pharmacist attend counselling; or by advising that the Pharmacy Council dismiss the complaint.

As mentioned, the complaint may be dealt with by inquiry at a meeting of the Pharmacy Council. The council has broad powers to ‘inform itself on any matter in the way it thinks fit ... receive written or oral submissions ... proceed with as little formality and technicality, and as much expedition, as the requirements of this Law and proper consideration of the complaint permit.’ The proceedings are not bound by the rules of evidence and the complaint can be dealt with despite the absence of sample proofs © Elsevier Australia
the pharmacist or pharmacy student who are the subjects of the complaint. The Pharmacy Council is empowered to:[27]

- caution or reprimand the pharmacist or pharmacy student
- make an order against the pharmacist in relation to withholding or refunding payments in relation to fees to be charged or paid for the service that is the subject of the complaint
- impose specified conditions on the pharmacist’s or student’s registration
- order the pharmacist or pharmacy student to seek and undergo medical or psychiatric treatment or counselling
- order the pharmacist or student to complete an educational course specified by the council
- order reporting on the pharmacist’s practice at any time and in the way specified by the council
- order the pharmacist to seek and accept management advice in relation to their practice.

If the Pharmacy Council finds that the pharmacist has been guilty of unsatisfactory professional conduct, and there is no other order that is appropriate in the public interest, the council may impose a fine of not more than 50 penalty units. The Pharmacy Council is also empowered to recommend that the registration of the pharmacist, or pharmacy student, is suspended or cancelled when, based on the evidence, the council is satisfied that the pharmacist does not have sufficient physical or mental capacity to practise pharmacy or that the pharmacy student has an impairment.[28] Decisions of the Pharmacy Council must be in writing and made available within 30 days to the complainant, the pharmacist or pharmacy student, the PBA and any other person the council thinks fit.

When the Pharmacy Tribunal, based on the evidence or a guilty plea, finds the complaint about the pharmacist or pharmacy student proven, it may issue a caution or reprimand, impose conditions on their registration, order that they seek and undergo medical or psychiatric treatment or counselling and/or order that they successfully complete a specified educational course. In addition, the Pharmacy Tribunal may order that the pharmacist seek and accept management advice and report on their practice as required by the tribunal.[29] Consistent with the Pharmacy Council’s powers, the tribunal may impose a fine (not more than 250 penalty units) if the pharmacist has been found guilty of unsatisfactory professional conduct and there is no other order that is appropriate in the public interest.[30]

The Pharmacy Tribunal may also suspend or cancel the pharmacist’s registration if it is satisfied the pharmacist is not competent to practise, is guilty of professional misconduct, has been convicted of, or made the subject of, a criminal findings in circumstances that render the pharmacist unfit in the public interest to practise, or the pharmacist is not a suitable person for registration in the profession of pharmacy. In relation to a pharmacy student, the tribunal may suspend or cancel their registration if the student has been convicted of, or made the subject of, criminal findings that make the student unfit, in the public interest, to undertake clinical training in the profession or is otherwise not a suitable person to undertake clinical training. When the pharmacist or pharmacy student is found to have contravened a critical compliance order, or condition, the tribunal must cancel his or her registration.[31]
CHAPTER 7 • Investigation, discipline and legal proceedings

ProFESSIONAL MISCOnDUCT, UNPROFESSIONAL CONDUCT, UNSATISFACTORY PROFESSIONAL PERFORMANCE AND UNSATISFACTORY PROFESSIONAL CONDUCT

Both the National Law Act and the Health Practitioner Regulation National Law (NSW) No 86a define the term professional misconduct. In addition the National Law Act provides definitions for two other categories of conduct: unprofessional conduct and unsatisfactory professional performance. The NSW legislation refers to and defines the term unsatisfactory professional conduct in relation to regulated health practitioners. This term is not included in the National Law Act. These terms are also examined in case law where professional misconduct is regarded as a more serious category of misconduct than unprofessional conduct. This distinction was emphasised in the Tasmanian case of Adamson v Pharmacy Board (Tas) [2004] TASSC 32, where a pharmacist’s professional misconduct was defined as:

... behaviour on the part of a member of a profession that would reasonably be regarded as disgraceful or dishonest by members of that profession of good repute and competency.

Case scenario

A registered pharmacist is the sole proprietor and the pharmacist in charge of GoodPharm Pharmacy. The pharmacy is located in an urban suburb approximately 5 km from the city. From January 2007 to February 2008 the pharmacist ordered, and was supplied with, 14,025 packets of pseudoephedrine-based products. In April 2008 the pharmacy held two packets of pseudoephedrine-based products in stock and was able to produce documents allegedly accounting for the sale of 409 packets.

From 2006 pseudoephedrine-containing products have been classified as Schedule 3 poisons pursuant to the provisions of the Regulations in the jurisdiction in which the pharmacist operates his business. As a consequence of this classification the pharmacist is required to comply with the activities and documentation as set out in the Regulations in relation to pseudoephedrine-based products.

The pharmacist has failed to keep any (or any adequate) records in respect to the sale or supply of the products referred to. Consider the following questions:

- Is this conduct grounds for a notification (complaint)?
- What charges may be brought against the pharmacist?
- What is the disciplinary process in relation to his conduct?
- What are the possible outcomes of any disciplinary action taken against him?
Unprofessional conduct was defined as:

... conduct which may reasonably be held to violate, or fall short of, to a substantial degree, the standard of professional conduct observed or approved by members of the profession of good repute and competency.

In the matter of *Pharmacy Board of Australia v Smith* [2012] QCAT 186 the pharmacist dispensed to a single customer over an eight-month period: 84 Deca-Durabolin ampoules, 18 Deca-Durabolin Orgaject ampoules, 168 Primoteston Depot ampoules, 1200 Proviron tablets, 180 Sustanon ampoules and four Reandron ampoules. All of these medications have the potential for misuse and abuse and are recognised within the pharmacy profession as being the objects of illicit trade. The pharmacist conceded, and the Queensland Civil Administrative Tribunal (QCAT) found, that the pharmacist engaged in unsatisfactory professional conduct in that (at [4]):

- his conduct fell below the standard that might reasonably be expected of him by the public and his professional peers
- his conduct demonstrated incompetence or lack of adequate knowledge, skill, judgment or care in his practice of his profession
- he provided a person with health services of a kind that was excessive, unnecessary or not reasonably required for that person’s wellbeing.

An overview of the circumstances and the pharmacist’s behaviour serves to illustrate the basis for the finding of unsatisfactory professional conduct under the National Law Act. As an example, it was found that it would be unusual for a doctor to prescribe two or more different preparations of steroids of similar use and outcome to the same patient at the same time, that the volumes of the medications dispensed were in excess of quantities usually prescribed for each medicine and the frequency of dispensing was far in excess of normal dosage ranges (at paragraph [7]). The pharmacist confirmed that he had dispensed steroids to the same customer over three consecutive days and dispensed multiple steroids knowing that the customer had been supplied with the same particular medications only four days earlier. It was noted that although the doctor prescribing the medications was known to the pharmacist, he did not question the prescriptions with the doctor even though he had sufficient information to do so. The pharmacist conceded that he ought to have known that the quantity and combinations of restricted drugs he dispensed to the same customer were not necessary for a therapeutic purpose and he should have been alert to the possibility that the customer was diverting or abusing the steroids and ceased dispensing them until he had discussed the matter with the dispensing doctor (at paragraphs [10–11]). Judge Kingham (at paragraphs [5–6]) stated:

*A pharmacist’s primary concern must be the health and wellbeing of the customer and community. Pharmacists must promote judicious, appropriate, safe and effective use of medicine and be aware of the trends and patterns of use of commonly misused substances. This requires pharmacists to exercise professional judgment to prevent the supply of products likely to constitute an unacceptable hazard to health or supply unnecessary or excessive quantities of medicines with potential for abuse or dependency.*

**Natural justice**

Pharmacy registering authorities must act in accordance with the principles of natural justice throughout the investigative and disciplinary processes. Natural justice
was described in *Byrne v Kinematograph Renters’ Society* [1958] 2 All ER 579 by Harman J as:

... the person accused should know the nature of an accusation made; secondly he should be given an opportunity to state his case; and thirdly of course that the tribunal should act in good faith. I do not think that there is anything more.

The notion of natural justice is to ensure that the proceedings are conducted fairly, impartially and without prejudice. The pharmacy registering authority must therefore provide the pharmacist, against whom the accusations are made, with a clear statement of the actual charge, adequate time to prepare a submission in response to the charge and the right to be heard on all allegations.

**Hearings**

A pharmacist should be able to put his or her case verbally, although there may be circumstances where written submissions may be sufficient. Although the pharmacist may want to have legal representation before a council, a panel, a committee or at the hearing, the right to legal representation is determined by the relevant legislation. The legislative provisions will set out whether legal representation is a right or whether the pharmacist must seek permission (leave) to be represented. It may also be the case that for panels or committees hearing matters of a less serious nature a legal representative may be present to advise the pharmacist but not present on his or her behalf.

**Evidence and standard of proof**

Both the National Law Act and the Health Practitioner National Law (NSW) entrusts the disciplinary entities with broad discretionary powers relating to the amount of evidence, the type of evidence and the source of the evidence that may be admitted into the proceedings for consideration in determining the outcome of any matter.

The rules of evidence do not strictly apply in disciplinary proceedings involving health professionals.⁴² Therefore, a board, disciplinary committee, panel and even a tribunal may admit and inform itself of matters that, in the judicial adversarial process, would be excluded from consideration based on the inadmissibility of the content. The disciplinary body therefore has the potential to admit and consider a broader range of information or materials than that which may come before a court. However, although the rules of evidence are not mandated in disciplinary proceedings, they generally provide guidance in terms of fairness and the general conduct of proceedings.⁴³

As a general principle, the admissibility of evidence is determined initially on the relevance of the information to the facts in issue and, then, in weighing up the probative value of having the information (the extent to which admitting the evidence would assist in reaching the truth) against the prejudicial impact (the extent to which it operates against the defendant) that the information may have on the determination.

The common law test is used frequently in the form of ‘peer review’ evidence, as defined by Priestly JA in *Qidwai v Brown* [1984] 1 NSWLR 100 at 105–106:

*Whether the practitioner was in such breach of the written or unwritten rules of the profession as would reasonably incur the strong reprobation of professional brethren of good repute and competence.*
In all jurisdictions the standard of proof required for making a finding is the civil standard, 'on the balance of probabilities', and not the more onerous criminal standard of 'beyond reasonable doubt'. This is in accordance with the Briginshaw test that was defined in *Briginshaw v Briginshaw* (1938) 60 CLR 336, and is the standard followed in Australia regarding all disciplinary proceedings. The rationale for the lower standard is that the jurisdiction is protective towards the public, and a professional person may need to be excluded from practice in order to protect the public on the basis of facts that are impossible to prove 'beyond reasonable doubt'.[34] However, according to the Briginshaw case, the clarity of proof required to discharge the burden must reflect the seriousness of the charge.

**OUTCOMES OF DISCIPLINARY ACTION**

Prior to the introduction of the National Law Act mutual recognition legislation gave effect to the results of disciplinary action in the different states and territories. Therefore, in the case where a pharmacist’s registration is cancelled or suspended by a registering authority as a result of disciplinary action, authorities in other jurisdictions, whether interstate or overseas, were able to give effect to that order if they so chose.

Although the processes of investigating and disciplining registered health practitioners and students have been standardised under the national scheme (with the exception of NSW) it is still the case that disciplinary hearings are conducted before individual tribunals within each state and territory. At the time of writing research is being undertaken into the outcomes of disciplinary hearings (involving regulated health professionals) before the responsible tribunals under the National Law Act, and the professional tribunals in NSW, to gain an overview of the outcomes.

In general, disciplinary entities and tribunals are able to apply a broader range of penalties that are more remedial than are those available through the courts.[35] Disciplinary sanctions imposed on health professionals through regulatory processes do not follow a punitive approach but rather seek to protect the public by specific and general deterrence. Therefore, one of the aims of disciplinary actions is to deter other pharmacists from similar behaviour. Additionally, disciplinary outcomes also serve to maintain the reputation and standing of health professionals.[36] These two outcomes need to be balanced.

**Severity of penalties imposed**

Weighing the interests of practitioners against the interests of the public may cause some difficulty. This is evident from the decisions of two disciplinary cases that have been appealed to the Supreme Court of Victoria following the imposition of sanctions by the Pharmacy Board of Victoria. Although the court upheld the board’s decisions in the two cases regarding the pharmacists’ conduct, it did not support the penalties imposed by the board, as these were considered too severe, and less harsh penalties were subsequently imposed.

*Mercer v Pharmacy Board (Vic)* [1968] VR 72 dealt with a pharmacist who was absent from the pharmacy while it was open and professional services were provided. The court upheld the board’s finding that the pharmacist had been guilty of conduct discreditable to a pharmaceutical chemist, but found the cancellation of registration penalty imposed by the board too severe. Pape J made the following comment in considering the board’s penalty (at [93]):
I am conscious of the fact that the board, composed as it is of pharmaceutical chemists who are charged by statute with preserving discipline among pharmaceutical chemists, is infinitely better able to assess the appropriate penalty than I am, and I am not anxious to undermine their authority or discourage them from taking firm action in the interest of the public and the profession nor am I anxious to take any action which might be construed as an indication that I do not regard the conduct proved against the appellant as anything but most serious.

However (at [94]):

There are, I think, a number of factors which would indicate that the penalty imposed by the board (which is the most severe penalty that it could impose) was excessive in all the circumstances.

The court instead imposed a four-week suspension.

The case of Ha v Pharmacy Board (Vic) 18 VAR 465; [2002] VSC 322 did not directly involve the practice of pharmacy but, rather, as stated by Gillard J (at [89]), was brought to ‘uphold the law’. Mr Ha, a pharmacist, indecently assaulted two young females (14 and 20 years old) during job interviews. In the Supreme Court of Victoria, Gillard J acknowledged (at [84]) that, in determining:

... the standard that one would expect of the reasonable competent pharmacist of the good character and reputation expected of a pharmacist, the members of the board are usually in a better position than this Court to make an assessment of those matters, and in those circumstances, the Court should attach substantial weight to their findings.

Gillard J further observed (at [86]) that the inappropriate behaviour of the appellant:

... was not confined to the practice of pharmacy ... However, his conduct does have a connection with the practice of pharmacy in that he was able, by reason of his position as a pharmacist, to deceitfully induce the potential employees to go along with his investigation because, as a pharmacist, he was concerned about the theft of drugs.

He postulated that the Pharmacy Board of Victoria had a joint focus, namely to protect the public and protect the reputation of the profession itself. However, Gillard J considered the order of the board that the pharmacist’s registration be suspended and concluded that, in this case, suspension was not necessarily to protect the public but rather to maintain the profession’s standing. He held (at [84]):

[W]here the issues involve matters that do not depend upon the practice of pharmacy, then the Court is in as good a position as the board to make its own assessment of the penalty.

Therefore, although the court upheld the board’s finding of professional misconduct, it found the three months’ suspension unreasonable considering the circumstances, and imposed a less severe penalty. Mr Ha was fined $1500 and given a two-year community-based order to perform unpaid community work, and to undergo psychological or psychiatric treatment as directed.

As part of the disciplinary process is to maintain appropriate standards within the profession and to maintain public confidence in health professionals, it can be questioned whether the Supreme Court of Victoria’s lighter sanctions in these two cases were in the best interest of the public, or whether they acted to deter other pharmacists. The court has not consistently imposed less severe sanctions than the
board. In *Loewy v Pharmacy Board (Vic)* [1991] VSC 11301 the court upheld the Pharmacy Board of Victoria’s penalties and dismissed an appeal against a three-month suspension for Mr Loewy. This case dealt with the supply of huge quantities of ephedrine to customers. Hedigan J, in his decision as to whether the penalty was appropriate, held (at [32]):

> With respect to penalty, the court ought to give weight to the views formed by the relevant professional body created by the Act of Parliament to exercise supervision over the conduct of the members of the relevant profession. Those views have been expressed by the Pharmacy Board and I take them into account.

Another interesting decision was the Supreme Court of Tasmania’s decision to increase the penalty imposed on Mr Adamson in *Adamson v Pharmacy Board (Tas)* [2004] TASSC 32. This case involved a dispensing error whereby the pharmacist dispensed prednisolone 25 mg instead of 5 mg and thereafter incorrectly dispensed a repeat supply of the same tablets. The Pharmacy Board of Tasmania’s order was to allow Mr Adamson to continue to practise but only under the supervision of another pharmacist. However, Mr Adamson was the owner of the pharmacy and the court found that it would therefore not be appropriate to make him work under the supervision of an employee. As Mr Adamson was already 80 years old, the court held that his name be removed from the register but, in order to enable the sale of his pharmacy, deferred the deregistration until a later date. Mr Adamson was not allowed to dispense medication during the deferral of his deregistration.

The determination of appropriate sanctions is a complicated issue that will always be controversial; what may be an appropriate sanction in one case may not be so in another case involving a similar breach. The two outcomes that need to be achieved – namely, the protection of the public and the maintenance of professional standards – must be carefully considered and an appropriate balance struck.

**Publicity of outcomes**

An important function of professional disciplinary mechanisms is the publicity given to breaches.[37] It is important that pharmacists are informed of disciplinary outcomes to enable them to predict the consequences of professional misconduct, unprofessional conduct, unsatisfactory performance or unsatisfactory professional conduct. Publishing disciplinary decisions therefore serves to educate other pharmacists regarding practice requirements and the disciplinary process. An analysis of the impact of publishing the Royal Pharmaceutical Society of Great Britain Statutory Committee’s decisions in the *Pharmaceutical Journal* indicated that publication served to inform and deter other pharmacists from similar conduct and played a role in keeping the number of persistent offenders low.[38]

A number of the Australian jurisdictions make public the disciplinary case outcomes on the Australian Legal Information Institute (AustLII) website or the individual state and territory government websites.

**Case examples**

The following legal cases appear under a number of practice headings and illustrate the range of case law relating to pharmacy practice accumulating in Australia, with a few references to international cases.
Dispensing errors

While the number of dispensing errors is small compared with the number of prescriptions dispensed, any mistake has the potential to cause harm to a patient. Dispensing errors represent a significant proportion of disciplinary cases, which is indicative of the percentage of time pharmacists are occupied with the activity of dispensing and the significance of the dispensing workload.

A 2005 survey of complaints received by the Pharmacy Board of Victoria indicated that over a 78-month period covering 1 July 1998 to 31 December 2004, 45 per cent (73) of the 162 complaints received by the board were associated with dispensing errors.[39] Labelling errors accounted for 21 per cent and selection errors for 74 per cent of the complaints. The remaining errors were either the dispensing of expired medicines, or the wrong quantity.

More than 50 per cent of dispensing errors reported to Pharmaceutical Defence Limited (PDL) relate to human error.[40] Regarding the most common pharmacy dispensing errors, PDL identified the two most frequent causes as selecting the incorrect strength of a medicine, and selecting the incorrect product.[41]

Although most dispensing errors do not cause serious harm, others can have serious consequences. One Queensland case involved the death of a small child as a result of a methadone overdose. As discussed in Chapter 4, the pharmacist incorrectly administered 10 take-away methadone doses to a registered addict in a single bottle rather than separate bottles. Additionally, the pharmacist did not use a child-resistant cap on the bottle, or dilute the take-away doses as was required. The child subsequently swallowed the methadone.

The pharmacist was suspended from the register for a period of three years.

A NSW coroner made specific comments about a pharmacist’s responsibility to scrutinise prescriptions and intervene if necessary. These comments followed the death of a 17-year-old female after being prescribed and dispensed an overdose of the opioid Kapanol with the active ingredient morphine:[42]

*I have formed the view that [the pharmacist] did not pay sufficient heed to that part of his professional role as a pharmacist to scrutinise prescriptions presented to him. He has an independent, professional role to scrutinise and consider every prescription presented to him. He seems to have allowed this aspect of his professional behaviour to be subservient to that of the prescribing doctor.

The public expects that the pharmacist to whom a prescription is presented will act as more than a mere dispenser. The public expects that the pharmacist will act in concert with the medical practitioner whilst performing an independent, scrutinising role.

One hopes that (the pharmacist) examines his practices and attitudes and brings them into line with the proper, professional role of an independent pharmacist. That is not to merely dispense and slavishly follow the directions of a medical practitioner but to scrutinise, question, consider and then act to dispense only if satisfied after those procedures are adopted in relation to each prescription.

In another matter, Daniew [2007] NSWPB 5 (14 November 2007), a pharmacist dispensed five morphine tartrate ampoules 120 mg/1.5 mL for a patient with chronic back pain. The patient self-injected one ampoule, resulting in his death the following morning from a morphine overdose. The Pharmacy Board of New South Wales report on the matter stated:
The complaint of professional misconduct concerned the dispensing of a drug of addiction, morphine tartrate ampoules 120 mg/1.5 mL by the pharmacist on or about 29 September 2004, for Mr Wayne Ritchie on a prescription written by Dr Garry Gow. The pharmacist was employed at the relevant time as the pharmacist in charge and is an experienced pharmacist with no prior disciplinary history. Shortly after the morphine tartrate ampoules were dispensed by the pharmacist, Mr Ritchie self injected an ampoule and died. The direct cause of death was a morphine overdose.

The complaint alleged that the morphine tartrate ampoules had been dispensed in circumstances where this was the first occasion in which a drug of addiction had been dispensed for Mr Ritchie at the pharmacy. Mr Ritchie was known to the pharmacist. It was alleged that the pharmacist failed to make appropriate inquiries of the prescriber, Dr Gow, and of Mr Ritchie and that contrary to clause 109 of the Poisons and Therapeutic Goods Regulation 2002, the pharmacist supplied the morphine tartrate ampoules in an excessive quantity that did not accord with appropriate recognised therapeutic standards.[43]

The Professional Standards Committee found that the particulars had been proven and made a number of orders including cautioning the respondent against ignoring her legal and professional obligations in the dispensing of drugs of addiction ordered on the prescription of a medical practitioner – in particular, the need to exercise professional judgment to satisfy herself on each occasion that the medication ordered is in a quantity and for a purpose in accordance with recognised therapeutic standards.

Similar to Australia, various British cases highlight pharmacists’ responsibility regarding dispensing and some of the cases are often referred to in the literature. Prendergast v Sam & Dee Ltd (1989) 1 MLR 36 is of relevance regarding dispensing errors and the court held that a pharmacist has a responsibility to contact the prescriber if in doubt about what is written on the prescription. In this case the pharmacist misread the doctor’s handwriting and the pharmacist read and dispensed Daonil (glibenclamide) instead of Amoxil (amoxicillin). The patient, who was not a diabetic, subsequently suffered hypoglycaemia and irreversible brain damage.

The British case of Dwyer v Roderick (1983) 127 SJ 805 is usually referred to as the Migril case. In this case the doctor negligently directed the patient to take an overdose of Migril (ergotamine) and the pharmacist failed to spot the error. The patient subsequently took an overdose and suffered gangrene in both feet, requiring extensive surgery. Justice Stuart-Smith rejected the pharmacist’s argument that his position is secondary to that of the doctor; the court held that it was the pharmacist’s duty to ensure not only that the prescription was correctly dispensed, but also that it was suitable for the particular patient:

[P]harmacists have to exercise an independent judgement to ensure that the drug is appropriate for the patient as well as that it conforms to the physician’s requirements.

Mr Justice Keith confirmed the court’s approach towards pharmacists’ liability to ensure the dosage is correct in the High Court case of Horton v Lloyds Pharmacy Ltd (2006). In this case the plaintiff, an American lawyer, Cathy Horton, had an incorrect prescription prescribed by a British doctor in July 2001, and the pharmacist at Lloyds Pharmacy dispensed the prescription without questioning the dose. The prescription was for dexamethasone 4 mg daily instead of her maintenance dose of 0.5 mg daily.
– eight times the dose that she had taken for a number of years. On her return to the United States, a doctor continued to prescribe 4 mg daily after reading the dispensing label. By the end of October 2001, Ms Horton had developed Cushing’s syndrome and subsequently required multiple hospital admissions and was unfit for work for many months. She claimed that the negligent over-dispensing ‘wrecked’ her life and robbed her of the chance of making millions from a new business venture. The judge ruled that the accepted wisdom was that pharmacists should consider whether a prescribed medication was suitable for the patient. It should have occurred to the pharmacist that the dose was eight times the strength of those that had been dispensed on seven previous occasions. It was accepted that the deterioration in Ms Horton’s health did not result from the tablets dispensed by Lloyds Pharmacy. However, it was ruled that there was a direct causal link between the pharmacist’s failure to question the prescription and the American doctor providing the 4 mg daily dose. Ms Horton claimed £5 million in damages.

In each of these cases the British courts held that pharmacists possess expertise regarding the supply of medications, and that reliance for that expertise is placed on them by patients and prescribers. This approach has also been followed in the United States, for example, in Riff v Morgan Pharmacy, 508 A.2d 1247 (Pa. Super. Ct. 1986), a case that is very similar to the Migril case. In this case the jury’s verdict was upheld on appeal, awarding 65 per cent fault against the pharmacist for not warning a patient against the maximum dosage for the dangerous and potentially toxic migraine medicine, namely Cafergot (ergotamine) suppositories. The pharmacy dispensed the medication with the prescriber’s directions on the label to use one by rectum every four hours, with no maximum dose information. As a result of overuse, the plaintiff’s foot suffered permanent damage, causing the patient constant discomfort. The court reviewed pharmacists’ training, internship requirements and comprehensive licensure examination and stated that:

[A] pharmacist is a professional. In the performance of his professional duties, he will be held to the standard of care, skill and intelligence, which ordinarily characterises the profession. In judging the degree of skill, consideration will be made of the advanced state of the profession at the time of the injury.[44]

These cases clearly indicate the responsibility and potential legal liability on pharmacists during dispensing.

Generic substitution

Generic substitution increases the risk that medication errors will not be identified by patients because patients may assume that the incorrectly dispensed medicine is a generic version of the correct medicine. A Victorian pharmacy error, which led to the hospitalisation of a seven-year-old asthmatic boy, involved the incorrect dispensing of Risperdal (risperidone) instead of Redipred (prednisolone). The boy’s parents subsequently gave him large doses of risperidone for his asthma. An important factor that contributed to this potentially fatal incident was the fact that the parents did not identify the error, even though the boy’s father said that they had been issued at least two bottles of the wrong medication by their pharmacy. He further commented:

*It comes in the same size bottle, it’s liquid and looks the same. We just thought this other drug was a generic brand of the same drug.*[46]
These comments suggest system failures in both the dispensing and the patient counselling processes, and the need to educate patients to focus on active ingredients rather than on the brand names.

It has been suggested in the United States that courts should more closely examine pharmacists’ expanded role regarding cases involving generic substitution. This is a result of two reported appellate court cases involving drug product selection in which pharmacists were sued for damages. In Ulman v Grant (1982) 450 NYS 2d 955, the patient presented a prescription to a pharmacy for Septra DS, a specific brand of sulphamethoxazole trimethoprim. The prescriber wrote ‘substitution permitted’ on the prescription, and the pharmacy dispensed Bactrim DS. The prescriber suffered an adverse reaction and sued the pharmacy.

In Bichler v Willing (1977) 397 NYS 2d 57 a pregnant mother was prescribed diethylstilbestrol (DES) and the pharmacy dispensed the Eli Lilly brand. The daughter of the mother claimed severe and permanent injury due to the medicine, and sued the pharmacy.

It is important to note that claims against health professionals in the United States are more common than negligence claims in Australia and the United Kingdom. This is mainly because in the United States there are no patient cost disincentives to initiate legal action, for example, an absence of the ‘loser pays’ legal cost rule. However, these cases do provide some insight as the courts had to consider whether the pharmacist’s choice of a specific brand would have made a difference in determining their liability. The courts held that a pharmacist is not negligent unless the pharmacist knowingly dispenses a medication that is inferior or defective. Hence, if the generic medicine is not inferior or defective, the injury is not foreseeable. Therefore, both plaintiffs in these cases were unsuccessful in establishing pharmacist liability. However, it has been argued that these cases were considered before the role of pharmacists had expanded, and that today’s courts would give closer examination to pharmacists’ expanded role in selecting an appropriate generic product. An in-depth analysis of the theories of potential pharmacist liability and claims of professional negligence has subsequently been undertaken by legal and pharmacy practice experts in the United States. The authors concluded that pharmacists undertake new responsibilities under medication selection law (common law and legislation), and might be exposed to liability if injuries were to occur when generic medicines were substituted for prescribed brand medicines. Three possible theories were identified under which pharmacies might be held liable for injuries sustained in medication product selection situations: negligence; express or implied warranties; or strict product liability.

It is not known which theories would apply in Australia, as there is a lack of case law, and therefore precedent. However, it is clear that the increase in generic dispensing places additional time constraints on pharmacists. There is also an increased need for professional judgment, and hence increased risk of error.

Lack of advice or written information

Providing advice fulfils an important risk management activity. However, reviews of investigations in both Queensland and NSW indicated that counselling had not been provided by the pharmacist in the majority of dispensing error cases. It was estimated that at least 25 per cent of medication errors might have been detected before handing out the medication. Although there are circumstances where there is little need for counselling to be provided when a prescription is dispensed (where,
for example, a patient received repeat medication for treating a chronic condition), it is important in such circumstances that pharmacists use professional judgment in making the decision not to counsel.

In the case where a pharmacist has not counselled a patient or carer and the patient suffers a medication-related adverse event, it would be reasonable in a disciplinary investigation to establish whether the lack of counselling contributed to the event and whether the professional conduct in such a circumstance was ‘of a lesser standard than those expected,’ or whether the pharmacist’s conduct demonstrates a lack of judgment or care. In a 2005 Pharmacists Board of Queensland investigation involving the dispensing of the cytotoxic medicine methotrexate, it was found that lack of counselling by the pharmacist and the failure to provide any written information had significantly contributed to the patient’s dosing error.

Pharmacists could potentially be liable for not providing appropriate written information in the case of an adverse event. This legal liability was demonstrated by the American case of *Cottam v CVS Pharmacy* (2002) 436 Mass 316, 764, NE 2d 814 where the court found the pharmacy 51 per cent negligent for not warning a patient of priapism as a potential side effect of the antidepressant trazodone; the patient was left permanently impotent as a result of using the medicine. The court found that the pharmacy voluntarily assumed a duty to provide information, advice and warnings to a patient as it was the pharmacy’s normal practice to issue a ‘long form’ list of side effects when a medicine was dispensed for the first time. By giving out a list of information as part of normal practice the pharmacy voluntarily assumed a duty to warn and in so doing had to perform that duty with due care. The court found that where the information provided could be reasonably understood by the patient as a complete list of side effects, it is appropriate to impose the duty to warn as to all potential side effects. The Illinois Appellate Court in *Frye v Medicare Glaser Corp.* (1992) 605 Ill NE 2d 557 similarly ruled that a plaintiff may maintain an action against a pharmacist who voluntarily assumes a duty to warn of a medicine’s adverse reactions but does so in an incomplete manner.

In the matter of *Sedrak* [2007] NSWPB 4 (10 October 2007), the Pharmacy Board of New South Wales brought disciplinary action against a pharmacist, in part for the lack of adequate counselling on three occasions that led to complaints. The board report on the matter stated:

> The complaint of professional misconduct encompassed events arising from the dispensing of paediatric prescriptions by the pharmacist, the sole proprietor and pharmacist in charge of the pharmacy. In the first incident the medication for a 20 months old [sic] infant was placed in a box containing a directions label for another adult patient. The child had an adverse reaction to the medication. The complaint alleged certain failures in the pharmacist’s dispensing process, including a failure to counsel. In the second incident the pharmacist dispensed a medication for a 10 year old girl, which had an approved indication for the treatment of a prostatic condition, without verifying with the prescriber the intended use of the medication in a female child or satisfying himself as to the therapeutic purpose of such supply contrary to clause 53 of the Poisons and Therapeutic Goods Regulation 2002. The pharmacist had also failed to counsel the mother of the patient as to the dosage and administration of the medication. In the third incident the pharmacist had supplied antibiotic eye drops and eye ointment for a 20 months old [sic] child, without a prescription from a medical practitioner, contrary to Section 10(3) of the...
Poisons and Therapeutic Goods Act 1966. The pharmacist admitted some of the particulars of the complaint. No witnesses were called for cross examination by the Respondent.\[54]\]

The dispensed medicines involved in the three instances were prednisolone, tamsulosin (used for prostatic hyperplasia) and Chlorsig eye ointment and Chlorsig eye drops (active ingredient chloramphenicol) respectively. The Professional Standards Committee found these matters were proven to its satisfaction and the pharmacist was:

\[55]\]

... reprimanded and educative orders were imposed including the submission of written dispensing process, a related tutorial presentation and inspection/audit of such procedures. The pharmacist was required to obtain and maintain Quality Care Pharmacy Program Accreditation for any pharmacy in which he has a pecuniary interest with annual assessments for 3 years following accreditation and assessment results being provided to the board. The costs of complying with these orders are to be borne by the pharmacist.\[55]\]

Supply of pseudoephedrine and anabolic steroids

In cases involving the excessive supply of pseudoephedrine, it was found that multiple packs were supplied to individuals at a frequency not therapeutically justifiable, or that the drug was for non-therapeutic purposes. Despite the fact that the pharmacists were aware that pseudoephedrine is readily capable of abuse or misuse in the manufacture of amphetamines, it was supplied ‘in quantities contrary to responsible pharmacy practice’ and ‘without regard or sufficient regard to the risk to the public arising from the side-effects of abuse or misuse of the drug’\[56]\]

The fact that pharmacists can be imprisoned for illegally supplying pseudoephedrine indicates the significance of the responsibility placed on pharmacists to supply these products responsibly, and the expectation that pharmacists will follow the guidelines. As stated by O’Brien in the matter of Adrian Lim v Pharmacists Board of Queensland, Health Practitioners Tribunal, 11 December 2001:

\[57]\]

... in the Tribunal’s view that the order made is one which is calculated to maintain public confidence in the profession and in the system of disciplinary administration. There is also the need to remind other practitioners of the consequences of such transgressions.\[57]\]

In the matter of Bevan Honke v Pharmacists Board of Queensland, Health Practitioners Tribunal, 14 December 2001, O’Brien stated:

Having consulted my assessors I have concluded that a pharmacist, entrusted with the responsibility of selling and dispensing drugs which are capable of such abuse, must exercise a greater level of care than that which was demonstrated by the registrant in this case. So much is expected by the public and by other members of the profession.\[58]\]

Richards addressed the seriousness of the breach of public trust in sanctioning or ‘punishing’ the pharmacist in Ho Sum Lau v Pharmacists Board of Queensland, Health Practitioners Tribunal, 27 October 2003:

\[59]\]

It is trite to say that a professional who uses his profession to supply drugs to people of whom he is aware are manufacturing illegal substances
commits a very serious breach of the law and a serious breach of his professional standards. So a significant punishment must be imposed in the circumstances.\[59\]

A number of matters involving pseudoephedrine were considered by the Pharmacy Board of New South Wales from 2004 to the present day, including: Paek [2008] NSWPB 3 (12 March 2008); Huynh [2008] NSWPB 2 (9 January 2008); Moleta [2007] NSWPB 2 (12 September 2007); War [2008] NSWPB 5 (11 June 2008); Rodger [2007] NSWPB 3 (12 September 2007); Waskin [2005] NSWPB 3 (14 December 2005); Barone [2004] NSWPB 1 (14 July 2004); and Ton [2004] NSWPB 2 (8 December 2004). The penalties imposed in these cases ranged from caution and reprimand to suspension and cancellation, in many cases with the addition of a fine. Where caution, reprimand and suspension were involved the pharmacist was often also required to undertake an ethics course, undergo forensic assessment, undertake continuing education and prepare a paper for presentation to the board.

These cases demonstrate the consistent approach followed by courts and other disciplinary instruments regarding the requirement that pharmacists follow legislative provisions that guide the practice of pharmacy and endorsed practice standards.

Another feature of disciplinary action has been matters about the supply of anabolic androgenic steroid preparations, where there has been little due regard by some pharmacists to recognised therapeutic standards or where the pharmacist knew, or ought to have known, that the substances were being abused for body building purposes.

The matters of Pahos, Leros & Mesiti [2006] NSWPB 1 (8 March 2006) involved the supply of anabolic androgenic steroids to more than 100 patients between February 1999 and June 2000. In all three matters (heard concurrently) the pharmacists were severely reprimanded, fined $4400, required to complete at least 30 hours of continuing professional education in the years 2006, 2007 and 2008, prepare a paper to be presented to a peer group chosen by the board, maintain membership of the Pharmaceutical Society of Australia (PSA) and the Pharmacy Guild of Australia (PGA) for at least five years from the date of the orders, and to maintain Quality Care Program accreditation for their pharmacy.

In the matter of Gibson [2006] NSWPB 3 (10 May 2006), the pharmacist admitted to supplying Halotestin (fluoxymesterone) to 10 males when she was aware that the only approved indication for that medication was for palliative therapy in the case of advanced breast cancer. The board found the pharmacist displayed ‘an extremely cavalier attitude to the subject prescriptions dispensed and substantially compromised her professional obligations and responsibilities to the patient and the public in doing so\[60\].

The pharmacist was reprimanded, fined the maximum amount ($4400) and made to successfully complete a number of education programs.

Medication reviews

Significant duties and responsibilities are imposed on both community pharmacists and accredited pharmacists in providing medication review services. PDL identified potential risk areas in providing Home Medicines Review (HMR) services, which indicate ways in which a pharmacist may be deficient during the HMR process:\[61\]

- failing to perform the HMR with due care and diligence
- failing to respond to a request for an HMR in a timely manner
• failing to allocate sufficient resources to provide HMR services in an efficient and effective manner
• failing to perform the HMR at all.

A pharmacist’s participation in HMR activity results in increased responsibility and the potential for professional liability on accredited pharmacists. Litigation involving HMRs has already been reported, namely:

• One case emphasised the need for pharmacists to be careful in the manner in which patients’ individual traits and potential addictions are reported.
• Another case involved failure by the pharmacist to identify a drug–drug interaction and the patient subsequently suffered an adverse effect.
• A third case involved a general practitioner being sued by the estate of a deceased patient for not implementing the accredited pharmacist’s recommendations when the patient subsequently died. This case highlighted that there is also an increased potential for legal liability on general practitioners where they fail to consider an accredited pharmacist’s recommendations.

These incidents demonstrate the importance in following recommended medication review standards, guidelines, timeframes and protocols.

Extemporaneous compounding

In July 2007 the Pharmacy Board of Victoria found a pharmacist, who extemporaneously compounded a preparation that caused a patient to suffer a serious adverse reaction, guilty of professional misconduct and subsequently cancelled his registration. The facts of this case were that the pharmacist, on his own order, dispensed and supplied an extemporaneously prepared mouth ulcer gel by combining the contents of a 500 mg amoxycillin capsule/crushed tablet and the contents of a 500,000-unit nystatin capsule/crushed tablet with Bonjela, a proprietary medicine available without prescription. The amoxycillin was scheduled as a prescription-only medicine, for which the pharmacist did not have a prescription. The patient, who was allergic to penicillin, upon using the mouth ulcer, suffered an episode of acute penicillin anaphylaxis for which she had to be hospitalised.

PROFESSIONAL NEGLIGENCE

Disciplinary proceedings through AHPRA, the PBA and responsible tribunals are distinct from proceedings initiated through the adversarial court system. Action through the adversarial court system in the main involves a claim of medical negligence, which is a civil action initiated under the law of torts. The focus of civil litigation is to seek financial compensation. Although healthcare negligence litigation in Australia has historically mostly involved medical practitioners, the case law principles are applicable to all health professionals, and all health professionals are potentially liable for damage or injury sustained by a patient while under their care.

In terms of a civil action of negligence, a person alleging that a pharmacist was negligent must prove, on the balance of probabilities, that an act or omission was causally linked to an injury. For a claim to be successful there must have been a legal duty to take care on the part of the pharmacist, with the breach of which resulting in the person suffering damage. To succeed in a claim of negligence, the patient...
(plaintiff) must be able to establish, on a balance of probabilities, all four elements of a negligence action, namely that:

- a duty of care was owed by the pharmacist (defendant)
- there was a breach of that duty in that the pharmacist’s conduct fell below the required standard of care, which includes omitting or failing to do something, or by doing something incorrectly
- the breach of duty caused or materially contributed to the damage suffered – be it physical, mental or economic loss
- the loss or damage suffered was reasonably foreseeable.

The question of whether a duty of care was owed by a pharmacist in particular circumstances is determined by reference to the case law based on a general formula for the ‘duty’ in the English landmark case of *Donoghue v Stephenson* [1932] AC 562. In this case Lord Atkin defined persons to whom a duty of care is owed as (at [580]):

*You must take reasonable care to avoid acts or omissions which you can reasonably foresee would be likely to injure your neighbour. Who, then, in law is my neighbour? The answer seems to be – persons who are so closely and directly affected by my act that I ought reasonably to have them in contemplation as being so affected when I am directing my mind to the acts or omissions which are called in question.*

Following this argument it is clear that pharmacists have a duty of care to patients when providing professional services such as the dispensing of prescriptions, supplying over-the-counter (OTC) medicines or giving medication advice.

A breach of the duty of care refers to a failure on the part of the pharmacist to meet the standard of care that the law requires. The test to determine a breach is an objective one and the court will aim to determine whether a reasonable pharmacist failed to take reasonable precautions to avoid foreseeable risk. The benchmark in determining whether the conduct fell below the required standard is the ‘reasonable man’ test as defined in the British case of *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582 (at [586]):

*Where you get a situation which involves the use of some special skill or competence, then the test whether there has been negligence or not ... Is the standard of the ordinary skilled man exercising and professing to have that special skill ... In the case of a medical man, negligence means failure to act in accordance with the standards of reasonable competent medical men at the time ... a doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art ... merely because there is a body of opinion that would take a contrary view.*

This case involved assertions that both the standard of treatment and the information provided to the patient were deficient. According to the Bolam test the court would consider the professional standards applicable at the time and the practice followed by peers. In England, the Bolam test has been applied and extended beyond the diagnosis and treatment to the duty to warn of risks involved. The test is therefore applied to procedural and diagnostic errors, known as ‘technical blunder’ cases, as well as failure to warn of risks. However, in 1992 the High Court of Australia in *Rogers v Whitaker* (1992) 175 CLR 479 held that the Bolam principle had no application to giving advice or information. This case involved an extremely rare complication (sympathetic ophthalmia) about which the patient was not warned before she agreed to a procedure. The majority of the High Court held (at [494]):

*sample proofs © Elsevier Australia*
Whether a medical practitioner carries out a particular form of treatment in accordance with the appropriate standard of care is a question in the resolution of which responsible professional opinion will have an influential, often a decisive, role to play; whether the patient has been given all the relevant information to choose between undergoing and not undergoing the treatment is a question of a different order. Generally speaking, it is not a question the answer to which depends upon medical standards or practices. Except in those cases where there is a particular danger that the provision of all relevant information will harm an unusually nervous, disturbed or volatile patient, no special medical skill is involved in disclosing the information, including the risks attending the proposed treatment. Rather, the skill is communicating the relevant information to the patient in terms which are reasonably adequate for that purpose having regard to the patient’s apprehended capacity to understand that information.

The court made it clear that the information a professional ought to supply to a patient was patient-focused rather than clinician-focused. The decision in Rogers v Whitaker has since been used in Australia as a reference for allegations of negligence in the form of failure to advise, warn or inform a patient. The majority judgment was based on the opinion that as far as technical blunders are concerned, the doctor–patient relationship requires little contribution from the patient, as the medical practitioner should perform at a level requiring professional knowledge and skill. However, where the allegations involve providing information and advice, the medical practitioner should provide the appropriate amount and level of information necessary for the patient to reach a decision.

Health professionals therefore need to use their judgment in deciding what information to provide to patients and make an assessment as to whether the individual patient would be likely to attach significance to it.

The High Court of Australia’s rejection of the Bolam principle in cases of negligence involving failure to warn is of particular importance to pharmacists, as the role of a pharmacist increasingly extends to an advisory one through providing information. On a daily basis pharmacists need to counsel particular patients to ensure they are aware of, and understand, how to take prescribed and OTC medication, and to inform patients of relevant side effects as a result of taking the medication. The ultimate question to be considered by the court will be whether the conduct conformed to the standard of reasonable care demanded by the law. Hence, it will not be sufficient to prove that other pharmacists practise in a similar way if the practice is not to a standard that provides safe patient care.

Pharmacists therefore need to disclose real and foreseeable risks. However, Gaudron J in Rogers v Whitaker stated there is no obligation to disclose those risks that were ‘far-fetched’ and ‘fanciful’. Accordingly, pharmacists should use their judgment in disclosing, for example, medication side effect risks, and the gravity of potential harm to the patient should impact on the information provided.

As advances in technology expand the capabilities and responsibilities of pharmacists (such as computer systems that maintain patient profiles and automatically warn of drug interactions), it is important to evaluate potential liability in an effort to make the profession aware of potential litigation scenarios and to assist the profession to develop risk management procedures. However, Australian litigation involving negligent claims regarding pharmacists’ expertise in the more recently evolved areas of practice do not exist, and pharmacists’ legal liability towards patient care services has therefore not yet been well defined. [65]
In predicting pharmacists’ potential civil liability, two issues would need to be considered:

- the changed role of pharmacists, which increasingly extends to an advisory one through providing information as well as other roles (e.g. diagnosing and prescribing)
- the factors that will be taken into consideration by a court in making a determination of civil liability.

The courts would consider the precedent laid down through *Rogers v Whitaker*. However, the civil liability Acts in the various Australian states and territories are also considered, and accordingly will be discussed.

**Case scenario**

A patient was prescribed a migraine preparation containing ergotamine. On the prescription the doctor had ordered two tablets to be taken every four hours. It is well known that this medication interferes with circulation and potentially results in gangrene if taken excessively. Because of this recognised harm the usual dosage regimen restricted the amounts to be taken for any migraine attack. This dosage regimen was not included on the patient’s prescription. The pharmacist did not detect this omission nor did he contact the doctor to clarify the dosage. The patient consequentially suffered from gangrene, which required a limb to be amputated.

Consider the facts and identify:

- the legal action available to this patient in relation to her injuries
- the person against whom the action would be brought
- the relevant legislation
- the existence or otherwise of a duty of care
- whether there is a breach and how this would be determined
- the damage.

What is the likely outcome? Identify the relevant legislation for any additional action that may be taken against the pharmacist.

**Review of Australian negligence law**

The Review of the Law of Negligence in 2002 followed the Australian medical indemnity crisis, which was caused by an increased number of claims and amounts awarded in damages as the principal source of compensation for those injured through the fault of medical practitioners. The review was an attempt by Australian governments to reform common law and balance the scales between the interests of both plaintiffs and defendants. The objective was to implement the recommendations into a single statute that could be adopted uniformly in the various states and territories, thereby creating a consistent approach to the law governing liability and damages for personal injury and death resulting from negligence.\[66\]

As a result of the review, civil liability legislation was introduced in all Australian jurisdictions, as summarised in Table 7.1.
The following discussion uses the Civil Liability Act 2003 (Qld) (the Act) by way of illustration. For example, section 21 of the Act specifically addresses a doctor’s proactive and reactive duty to warn a patient or patient’s carer (substitute decision-maker) of risk before the patient undergoes any medical treatment, stating:

**Proactive and reactive duty of a doctor to warn of risk**

(a) information that a reasonable person in the patient’s position would, in the circumstances, require to enable the person to make a reasonable informed decision about whether to undergo the treatment or follow the advice;

(b) information that the doctor knows or ought reasonably to know the patient wants to be given before making the decision about whether to undergo the treatment or follow the advice.

This section refers specifically to doctors; hence it is not clear whether the standard would be applicable to other health professionals. In relation to the standard of care provided by a professional, the Act states in section 22:

**Standard of care for professionals**

(1) A professional does not breach a duty arising from the provision of a professional service if it is established that the professional acted in a way that (at the time the service was provided) was widely accepted by peer professional opinion by a significant number of respected practitioners in the field as competent professional practice.

(2) However, peer professional opinion can not be relied on for the purposes of this section if the court considers that the opinion is irrational or contrary to a written law.

(3) The fact that there are differing peer professional opinions widely accepted by a significant number of respected practitioners in the field concerning a matter does not prevent any 1 or more (or all) of the opinions being relied on for the purposes of this section.

(4) Peer professional opinion does not have to be universally accepted to be considered widely accepted.
(5) This section does not apply to liability arising in connection with the giving of (or the failure to give) a warning, advice or other information, in relation to the risk of harm to a person, that is associated with the provision by a professional of a professional service.

Of specific relevance is subsection (5) above, creating a vagueness regarding the approach to be followed by the court in the case of the giving of (or the failure to give) a warning, advice or other information. Therefore, the Act is unclear regarding the standard of care that will be applied to the duty of the pharmacist to warn patients of medication risks, and what evidence the court would use in the case of health professionals other than doctors.

Section 49B covers failed contraceptive procedure or contraceptive advice:

(1) This section applies if, following a contraceptive procedure to an individual or the giving of contraceptive advice to an individual, the individual gives birth to, or fathers, a child because of the breach of duty of a person in advising about, or performing, the procedure or giving the advice.

(2) A court can not award damages for economic loss arising out of the costs ordinarily associated with rearing or maintaining a child.

This section may be relevant to pharmacists in circumstances of supplying and giving advice regarding the use of contraceptives and the emergency post-coital contraceptive.

As the professional responsibility and subsequent legal liability of pharmacists in the evolving areas of practice is less predictable than the more routine focused technical functions that were primarily and traditionally a pharmacist’s main role, pharmacists’ potential liability regarding their expanding role has yet to be determined.

Availability of pharmacy incident data

As mentioned, there are very few reported Australian cases initiated through the adversarial court system that involve pharmacists in claims of professional negligence. This does not mean cases have not been initiated, but rather reflect the fact that pharmacist indemnity insurers tend to settle out of court.\[67\] PDL and Guild Insurance do not make available incident data. The reason quoted for this is because incident report information is considered ‘commercially sensitive’.\[68\] Tito already highlighted the unavailability of data in 1994 through the Australian Review of Professional Indemnity Arrangements:

Minimum information on claims data is publicly available in Australia ... the overall poor quality of the information and the difficulties the Professional Indemnity Review (PIR) faced in obtaining it indicate a need to work with the medical defence organisations (MDOs) to improve their data holdings ... the potential richness of the data held by MDOs in relation to their claims could be better used by the Colleges, medical schools, the profession and, in appropriate circumstances, the Commonwealth and State Governments, to ensure proper prevention and avoidance strategies are put in place.\[69\]

As indicated by Tito, incident data should be made available, as the information could be used to develop risk management processes and as examples in training graduates. Tito specifically commented on the absence of pharmacy claims data:
Detailed figures on the incidence of injuries and claims in pharmacy health care were not available. The incidence of injuries is said to be very low. Allegations of negligence against pharmacists do not appear to be high, indicating that the public will only complain to the Pharmacy Board if the incidence is regarded as severe.\footnote{70}

Incident reports provide only limited data regarding incident reports filed, and the reported information does not give statistics on the seriousness of errors.\footnote{71} Therefore, Australian data involving pharmacists’ incidents and claims are not publicly available. However, it could be argued that incident data provides valuable insights into the vulnerabilities of pharmacy service procedures and could identify areas for improvement. Therefore accumulated data could, and indeed should, be used to develop measures and systems to minimise the risk of medication errors and other incidents. Unfortunately, present attitudes relating to the availability of information precludes regulatory authorities or the profession from identifying practice shortcomings and this may need to be addressed.

**Procedures to follow after a mistake**

Complainants are often annoyed, not because an error or other mishap occurred, but because of a perception of an arrogant or off-hand manner of the pharmacist, leading them to feel that their concerns had been neither appreciated nor acknowledged. As a result, matters that could have been immediately resolved in an appropriate and professional manner by the pharmacist escalate to become the subject of a disciplinary investigation or civil action. The complainant is often left with the perception that he or she has been treated by the pharmacist in an ‘uncaring’ or ‘dismissive’ manner, and that the concern experienced by the patient, especially when some or all of the incorrectly dispensed medicine has been taken, has not been addressed. This causes patients to lose trust in the profession.

To provide some guidance to pharmacists in cases of a dispensing error, PDL has developed procedures to follow, as illustrated in Box 7.1.\footnote{72}
1. When presented with a complaint, ensure the matter is handled by the pharmacist.

2. Show concern and willingness to correct any error.

3. Check out the alleged error and, if established, replace the offending item immediately. Do not charge for the replacement. If it was dispensed at another pharmacy, check with that pharmacy and replace if possible. Take care not to compound the problem. Retain evidence if possible.

4. An apology couched in the correct way will not constitute an admission of liability. You should use either of the following two examples, which are ways of apologising without admitting liability: ‘I am sorry this has happened’; ‘I know this has caused you great pain/distress/anxiety.’

5. Determine whether any of the wrong drug has been used, or medication missed. Has any harm been suffered? Has any expense been incurred?
   - DO NOT OFFER COMPENSATION – This may be regarded as an attempt to bribe your way out of trouble.
   - DO NOT mention your insurance cover or the Pharmacy Board, as this will only sow the seeds of opportunity.

6. Show empathy with the patient. This gives them the opportunity to vent their feelings so you might learn where you truly stand.

7. At all times remain calm, sympathetic and cooperative. Advise that you will investigate how this occurred and take action to tighten procedures. Obtain a phone number and show an ongoing interest in the welfare of the patient.

8. Telephone PDL and report the problem. You will be advised of what further action to take. It is important that you report an incident where the wrong drug or wrong dose has been ingested, as a claim could be lodged at some future date.

9. Record the details and patient history and all relevant information in your diary. These notes may be extremely important in any subsequent defence of a claim.

10. If after the patient has left the pharmacy you suspect that an error has been made, act speedily to correct the problem, without causing any unnecessary alarm.

11. When a complaint is initiated by correspondence it is MOST IMPORTANT that you do not reply without first asking advice from PDL. Do not put anything in writing without advice from PDL.

12. If confronted by an investigating officer seeking information relating to drugs dispensed for a patient who has died or whose health has been compromised, it is recommended that PDL be contacted immediately so that legal advice can be provided.

13. When any incident occurs contact the prescriber as a matter of professional courtesy.
REVIEW QUESTIONS AND ACTIVITIES

1. Name the various mechanisms that consumers can follow in the case of a healthcare error.

2. Who is obliged to make a mandatory notification and upon what grounds?

3. What are the grounds upon which a voluntary notification may be lodged?

4. Describe the pharmacy disciplinary process followed in your jurisdiction. If you are a resident of NSW, how is the process in that state different from the national law?

5. Explain the difference between unprofessional conduct, professional misconduct, unsatisfactory professional performance and unsatisfactory professional conduct.

6. What is the purpose of a disciplinary process?

7. Discuss examples of disciplinary cases and outcomes in your jurisdiction.

8. What is meant by ‘natural justice’?

9. Explain rules of evidence as they apply in disciplinary proceedings.

10. Discuss pharmacists’ responsibility to advise patients about medicines supplied or dispensed.

11. List the elements required to be proven in a negligence claim.

12. Discuss how the civil liability legislation in your jurisdiction has affected negligence law.

13. How should pharmacy incident data be available to ensure safe and competent practice?

14. List and prioritise the procedures to be followed in the case of a dispensing error.

Further reading


Lau Yung Ming K. A duty of care: pharmacists’ negligence: implications for pharmacists and lessons arising, Allied Health Professions (5) 2003 at pp 1–8

Pharmacy Board of Australia: www.pharmacyboard.gov.au


References

1 Australian Capital Territory Human Rights Commission, New South Wales Health Care Complaints Commission, Northern Territory Health and Community Services Complaints Commission, Queensland Health Quality and Complaints
Commission, South Australia Health and Community Services Complaints Commission, Tasmania Health Complaints Commissioner, Victoria Office of the Health Services Commissioner, Western Australia Health and Disability Services Complaints Office.


3 Health Practitioner Regulation National Law Act 2009 s 142

4 Health Practitioner Regulation National Law Act 2009 s 143


6 Part 2, Section 4(7) Health Practitioner Regulation National Law (WA) 2010


8 ibid. at pp 57–8


10 Australian Health Practitioner Regulation Agency – Annual Report 2010–11 at p 55

11 ACT: Civil and Administrative Tribunal (ACAT); NT: Health Professional Review Tribunal; Qld: Civil and Administrative Tribunal (QCAT); SA: Health Practitioners Tribunal of South Australia; Tas: Health Practitioners Tribunal; Vic: Civil and Administrative Tribunal (VCAT); WA: State Administrative Tribunal

12 Health Practitioner Regulation National Law Act 2009 s 193(2)

13 Health Practitioner Regulation National Law Act 2009 s 196(1)

14 Health Practitioner Regulation National Law Act 2009 s 5

15 Health Practitioner Regulation National Law Act 2009 s 196(2)

16 Health Practitioner Regulation National Law Act 2009 s 197


18 Health Practitioner Regulation National Law (NSW) No 86a, s139B


20 Health Practitioner Regulation National Law (NSW) s 139E

21 Health Practitioner Regulation National Law (NSW) s 5


24 Health Practitioner Regulation National Law (NSW) s 237

25 Health Practitioner Regulation National Law (NSW) s 145D
26 Health Practitioner Regulation National Law (NSW) s 148C
27 Health Practitioner Regulation National Law (NSW) s 148E
28 Health Practitioner Regulation National Law (NSW) s 148G
29 Health Practitioner Regulation National Law (NSW) s 149A
30 Health Practitioner Regulation National Law (NSW) s 149B
31 Health Practitioner Regulation National Law (NSW) s 149C
33 ibid.
34 ibid.
35 ibid.
41 Pharmaceutical Defence Limited (PDL). Annual report. PDL, Hawthorn, 2005
42 Pharmacy Board of New South Wales. Responsibility to scrutinise and intervene. Bulletin. Pharmacy Board of New South Wales, Sydney, August 2003
43 DANIEW [2007] NSWPB 5, 14 Nov 2007
48 ibid.
49 ibid.
50 Low J. *Criteria for counselling*. Pharmaceutical Society of Australia (Qld branch). April/May 2004: 6
51 Pharmacy Board of New South Wales. *Criteria for counselling: the role of counselling in error minimisation*. Pharmacy Board of New South Wales, Sydney, August 2003
52 Low J. *Criteria for counselling*. Pharmaceutical Society of Australia (Qld branch). April/May 2004: 6
53 Brand P. *Labelling methotrexate tablets*. Letter. Pharmacists Board of Queensland, 2005


55 *Sedrak* [2007] NSWPB 4, 10 Oct 2007


57 *Lim v Pharmacists Board (Qld)* (unreported, Brisbane Health Practitioners Tribunal, 11 December 2001, No 3562/01) stated p 5

58 *Honke v Pharmacists Board (Qld)* (unreported, Brisbane Health Practitioners Tribunal, 14 December 2001, D2312 of 2001) stated p 8

59 *Lau v Pharmacists Board (Qld)* (unreported, Brisbane Health Practitioners Tribunal, 27 October 2003, No 1384/03) p 4

60 *Gibson* [2006] NSWPB 3 (10 May 2006), p 1


63 Pharmacy Board of Victoria. Formal hearing: Robert Wesley Symons, 4 July 2007


67 Pharmacy Board of Victoria. Formal hearing: Robert Wesley Symons, 4 July 2007

68 ibid.


70 ibid., p 20
