

AUSTRALIAN
PHARMACY
LAW AND
PRACTICE

Laetitia Hattingh
John Low
Kim Forrester

**2ND
EDITION**

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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.

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2013

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COMPETENCY STANDARDS (2010)

Chapter 1	1.1 Practise legally
Chapter 2	1.3 Deliver 'patient-centred' care 1.4 Manage quality and safety 1.5 Maintain and extend professional competence 6.3 Contribute to public and preventative health
Chapter 3	1.1 Practise legally 1.2 Practise to accepted standards 1.3 Deliver 'patient-centred' care 1.4 Manage quality and safety 2.2 Work to resolve problems
Chapter 4	1.1 Practise legally 1.2 Practise to accepted standards 1.3 Deliver 'patient-centred' care 1.4 Manage quality and safety 3.4 Manage quality service delivery
Chapter 5	1.1 Practise legally 1.2 Practise to accepted standards 1.5 Maintain and extend professional competence
Chapter 6	1.1 Practise legally 1.2 Practise to accepted standards 3.1 Provide leadership and organisational planning
Chapter 7	1.1 Practise legally 1.2 Practise to accepted standards 1.4 Manage quality and safety 3.4 Manage quality service delivery
Chapter 8	1.1 Practise legally 1.2 Practise to accepted standards 4.1 Undertake initial prescription assessment 4.3 Dispense prescribed medicines
Chapter 9	1.1 Practise legally 1.2 Practise to accepted standards 1.3 Deliver 'patient-centred' care 6.1 Assess primary health care needs
Chapter 10	1.1 Practise legally 1.2 Practise to accepted standards 5.1 Consider product requirements 7.2 Provide ongoing medication management

Chapter 11	1.1 Practise legally 1.2 Practise to accepted standards 1.5 Maintain and extend professional competence 4.1 Undertake initial prescription assessment 6.1 Assess primary health care needs
Chapter 12	1.1 Practise legally 2.5 Commitment to work and the workplace 2.7 Supervise personnel 3.3 Manage pharmacy infrastructure and resources 3.5 Provide a safe and secure work environment

ABBREVIATIONS

The following list includes commonly used abbreviations:

ACT	Australian Capital Territory
AHPRA	Australian Health Practitioner Regulation Agency
APC	Australian Pharmacy Council
CMI	Consumer Medicine Information
COAG	Council of Australian Governments
CPAs	Community Pharmacy Agreements
CPD	Continuing professional development
Cth	Commonwealth
HMR	Home Medicine Review
MMR	Medication Management Review
NMP	National Medicines Policy
NSW	New South Wales
NT	Northern Territory
OTC	over-the-counter (medicines)
PBA	Pharmacy Board of Australia
PBS	Pharmaceutical Benefits Scheme
PDL	Pharmaceutical Defence Limited
PGA	The Pharmacy Guild of Australia
PPIs	Pharmacy Practice Incentives
PSA	Pharmaceutical Society of Australia
Qld	Queensland
QUM	quality use of medicines
RMMR	Residential Medication Management Review
RPBS	Repatriation Pharmaceutical Benefits Scheme
SA	South Australia
SHPA	Society of Hospital Pharmacists of Australia
Tas	Tasmania
TGA	Therapeutic Goods Administration
Vic	Victoria
WA	Western Australia
WHO	World Health Organization

The following list includes law report citations and commonly used legal abbreviations.

A 2d	Atlantic Reporter
AC	Law Reports, Appeal Cases (UK)
ACJ	Acting Chief Justice
A Crim R	Australian Criminal Reports
AGPS	Australian Government Printing Service
ALD	Administrative Law Decisions
ALJ	Australian Law Journal
ALJR	Australian Law Journal Reports
ALR	Australian Law Reports
All ER	All England Law Reports (UK)
ANCI	Australian Nursing Council Inc.
ATPR	Australian Trade Practice Reports
Aust Torts Rep	Australian Torts Reports
CA	Court of Appeal
CAR	Commonwealth Arbitration Reports
CCH	Commercial Clearing House
Ch	English Reports, Chancery Division
CJ	Chief Justice
cl	clause
CLR	Commonwealth Law Reports
Cox CC	Cox's Criminal Cases (UK)
Cr App R	Criminal Appeal Reports
Crim LR	Criminal Law Review
DCJ	District Court Judge
DCR	District Court Reports (New South Wales)
DLR	Dominion Law Reports (Canada)
DPP	Director of Public Prosecutions
EOC	Equal Opportunity Cases
Eq	Equity
ER	English Reports
Exch	Law Reports, Exchequer Division (UK)
Fam LR	Family Law Reports
FCA	Federal Court of Australia
FCR	Federal Court Reports
FLC	Family Law Court
FLR	Federal Law Reports

ABBREVIATIONS

HCA	High Court of Australia
HL	House of Lords
IR	Industrial Reports
J, JJ	Justice(s) or Judge(s)
JA, JJA	Judge of Appeal, Judges of Appeal
JLM	Journal of Law and Medicine
KB	Law Reports, King's Bench Division (UK)
LJ	Lord Justice
MedLR	Medical Law Reports
MLR	Modern Law Review
MR	Master of the Rolls
NE	North Eastern Reports (US)
NLJ	New Law Journal
NSWCA	New South Wales Court of Appeal
NSWDC	New South Wales District Court
NSWDRC	New South Wales District Court Reports
NSWLR	New South Wales Law Reports
NSWPB	New South Wales Pharmacy Board
NSWR	New South Wales Reports
NSWSC	New South Wales Supreme Court
NTSC	Northern Territory Supreme Court
NTR	Northern Territory Reports
NW	North Western Reporter (US)
NZLR	New Zealand Law Reports
OR (2d)	Ontario Reports, second series
Pa. Super. Ct	Pennsylvania Superior Court
P 2d	Pacific Reporter, second series
QB	Law Reports, Queen's Bench Division (UK)
QC	Queen's Counsel
QCAT	Queensland Civil and Administrative Tribunal
QDC	Queensland District Court
Qd R	Queensland Reports
QSCR	Queensland Supreme Court Reports
QSR	Queensland State Reports
Reg(s)	regulation(s)
RPC	Reports of Patent Cases
s, ss	section, sections

SASR	South Australian State Reports
SJ	Solicitor's Journal
Syd LR	Sydney Law Review
TASSC	Tasmanian Supreme Court
VAR	Victorian Administrative Reports
VCAT	Victorian Civil and Administrative Tribunal
VLR	Victorian Law Reports
VR	Victoria Reports
VSC	Victorian Supreme Court
VSCA	Victoria Supreme Court of Appeal
WALR	Western Australia Law Reports
WAR	Western Australia Reports
WASC	Western Australia Supreme Court
WLR	Weekly Law Reports
WN (NSW)	Weekly Notes New South Wales