AN INVESTIGATION OF COMMUNITY PHARMACY RISK MANAGEMENT REGULATION AND PRACTICES IN THE CONTEXT OF AN EXPANDING ROLE

by

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ABSTRACT

The practice of pharmacy has changed over recent years with a greater emphasis on the patient and the provision of patient care services. This expanded role of pharmacists as medication managers impacts on their responsibility and potential legal liability. However, there is a dearth of information about the effectiveness of the regulation of community pharmacy practice and it is not known to what extent regulatory requirements support the changed role. Additionally, limited information is available with regard to risk management practices in community pharmacy in the context of this expanding role. This exploratory study hence examined risk management regulation and practices in community pharmacy.

The type and extent of potential liability was informed by officially recognised and endorsed professional practice standards and national and international case law. However, case law regarding the professional liability in civil actions of pharmacists is limited. Therefore, judicial decisions and legal principles generated through litigation involving other health professions provided the basis for extrapolating common principles that could be used to determine pharmacists’ potential liability.

Qualitative methodology was used and various methods of data gathering were employed to provide in-depth information about pharmacy regulation and risk management. The methods chosen provided information about the extent to which endorsed practice standards were applied in disciplinary proceedings by the Pharmacists Board of Queensland in cases of professional misconduct; the utilisation of practice standards by community pharmacists and the risk management procedures implemented by them; and the diversity of pharmacy practice regulatory requirements throughout Australian jurisdictions.

The analysis performed as part of the study provided information about the types of errors that lead to disciplinary action and insight into the factors underpinning the decisions of the Pharmacists Board of Queensland in making determinations and formulating outcomes. The findings of interviews with
community pharmacists demonstrated a need for them to increase their knowledge of the essential processes involved in practice services to improve risk management and ensure the provision of safe patient care services. Legislative inconsistencies between states and territories that directly impact on risk management in pharmacy practice were also highlighted, indicating a need for the harmonisation of regulation.

The study highlighted the need to improve risk management regulation and practices in community pharmacy in the context of expanding services. The initial base of evidence suggests implications for regulatory authorities, pharmacy professional organisations and individual practitioners, which are outlined in the final chapter.
STATEMENT OF ORIGINALITY

This work has not previously been submitted for a degree or diploma in any university. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person, except where due reference is made in the thesis itself.

__________________________
Laetitia Hattingh
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Publications and presentations developed and delivered as a result of the research (attached at the end of the thesis):

and poster presentation at the Australian College of Health Service Executives Queensland conference, Gold Coast, 19 – 20 May 2006

- **HL Hattingh**, N Smith, J Searle & K Forrester. “Pharmacists’ increased liability in the context of an expanding role”, abstract and oral presentation at the 16th World Congress on Medical Law, Toulouse in France, 7 – 11 August 2006


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Australian Capital Territory:
Civil Law (Wrongs) Act 2003 (ACT)
Civil Law (Wrongs) Amendment Act 2003 (ACT)
Health Professionals Act 2004 (ACT)
Poisons Act 1933 (ACT)
Poisons and Drug Act 1978 (ACT)
Poisons Regulation 1996 (ACT)

New South Wales:
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Pharmacy Act 1964 (NSW)
Pharmacy Practice Act 2006 (NSW)
Poisons and Therapeutic Goods Act 1966 (NSW)
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Northern Territory:
Health Practitioners Act 2004 (NT)
Personal Injuries (Civil Claims) Act 2003 (NT)
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Queensland:
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Drugs Misuse Act 1986 (Qld)
Freedom of Information Act 1992 (Qld)
Health Act 1937 (Qld)
Health (Drugs and Poisons) Regulation 1996 (Qld)
Health Practitioners (Professional Standards) Act 1999 (Qld)
Health Quality and Complaints Commission Act 2006 (Qld)
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Pharmacists Act 1991 (SA)
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Recreational Services (Limitation of Liability) Act 2002 (SA)
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Western Australia:

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Insurance Commission of WA Amendment Act 2002 (WA)
Pharmacists Bill 2006 (WA)
Pharmacy Act 1964 (WA)
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Poisons Regulations 1965 (WA)
Volunteers (Protection from Liability) Act 2002 (WA)
INTERNATIONAL

New Zealand
Health Practitioners’ Competency Act 2003 (NZ)

United Kingdom
Health Act 1999 (UK)
Medicines Act 1968 (UK)
Pharmacy Act 1954 (UK)

United States of America
Omnibus Budget Reconciliation Act of 1990 (OBRA) (USA)
GLOSSARY OF TERMS

Accredited pharmacist:
A pharmacist registered with the Australian Association of Consultant Pharmacy (AACP) or the Society of Hospital Pharmacists of Australia (SHPA) to conduct medication reviews (AACP https://www.aacp.com.au/).

Consumer Medicine Information (CMI) leaflets/sheets:
Brand-specific, manufacturer-produced written information about drug products that conforms with special provisions set out in the Therapeutic Goods Regulations 1990 (Cwlth), targeted at patients.

Controlled drugs:
Also referred to as ‘dangerous drugs’, ‘narcotics’ or Schedule 8 (S8) medicines. Substances that should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence (Department of Health and Ageing, 2006 p. 395).

Dispensing error:
An incident detected after the patient or agent has taken possession of the medication (Ashcroft et al., 2004).

Generic medicine:
Alternative brands of medicines that become available after the original brand’s patent expired. A generic medicine must be shown to be bioequivalent to another registered brand to be interchangeable with that brand (Smith & McLachlan, 2006).

Generic substitution:
Substituting one brand of a pharmaceutical with another brand, provided they are listed in the Schedule of Pharmaceutical Benefits as generic medicines and the prescriber has indicated that the substitution is permitted (Pharmaceutical Society of Australia, 2004).
Home Medicine Reviews (HMRs):
A government subsidised, consumer focused service with the goal of maximising patients' benefit from their medication and preventing medication-related problems through a team approach involving the patient’s general practitioner and preferred community pharmacy. (Medicare Australia http://www.hic.gov.au/providers/incentives_allowances/pharmacy_agreement/about_hmr.htm#2)

Medicines:
Also referred to as ‘drugs’. Therapeutic goods that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human or animal, as defined in the *Therapeutic Goods Act 1989* (Cwlth).

Near miss:
Any incident detected up to and including the point at which the medication was handed over to the patient or the patient’s representative (Ashcroft *et al.*, 2004).

Over-The-Counter (OTC) medicines:
Include both Pharmacy medicines (S2 medicines) and Pharmacist Only medicines (S3 medicines) and unscheduled medicines.

Pharmacist:
A person licensed to practise pharmacy under an Australian state or territory Act.

Pharmacist Only medicines:
Also referred to as Schedule 3 (S3) medicines. Substances, the safe use of which requires professional advice, but which should be available to the public from a pharmacist without a prescription (Department of Health and Ageing, 2006).
Pharmacy business:
In terms of the *Pharmacists Registration Act 2001* (Qld), means a business providing professional services but does not include a public sector hospital.

Pharmacy medicines:
Also referred to as **Schedule 2 (S2) medicines**. Substances, the safe use of which may require advice from a pharmacist, and which should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person (Department of Health and Ageing, 2006).

Pharmacy registering authorities:
Statutory bodies in all Australian states and territories established to protect public safety by ensuring health care is delivered by pharmacists in a professional, safe and competent manner (COPRA [http://www.copra.org.au/](http://www.copra.org.au/)).

Pharmacy self care cards:
Concise, action-oriented health information on fact cards designed by the Pharmaceutical Society of Australia (PSA), to be used by pharmacy staff to educate customers. Cards include useful counselling points, highlighting when referral is appropriate, and providing contact details for further sources of information (Pharmaceutical Society of Australia [http://www.psa.org.au/ecms.cfm?id=237](http://www.psa.org.au/ecms.cfm?id=237)).

Prescription medicines:
Also referred to as **Schedule 4 (S4) medicines**. Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe, and should be available from a pharmacist on prescription (Department of Health and Ageing, 2006).

Quality Care Pharmacy Program (QCPP):
The QCPP is a community pharmacy quality assurance program that was initially developed by the Guild in 1997 in consultation with the PSA and other industry stakeholders (Pharmacy Guild of Australia, 2006c). The program is dedicated to raising the standards of service provided to the consumer by
community pharmacies. It is based on a best practice business model to enable pharmacy owners that adopted the program to compete in an increasingly competitive health and retail environment.

**Residential Medication Management Reviews (RMMRs):**

**Risk management:**
The culture, processes and structures directed towards realising potential opportunities whilst managing adverse effects (Standards Association of Australia, 2004b).

**Vicarious liability:**
Holding one person liable for torts committed by others, even though that person was in no way to blame for the wrong and may not have been present when the wrong took place (Mullan, 2000 p. 233).
**ABBREVIATIONS**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>AACP</td>
<td>Australian Association of Consultant Pharmacy</td>
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<td>ACT</td>
<td>Australian Capital Territory</td>
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<tr>
<td>CMI</td>
<td>Consumer Medicine Information</td>
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<td>COAG</td>
<td>Council of Australian Governments</td>
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<tr>
<td>NCCTG</td>
<td>National Co-ordinating Committee on Therapeutic Goods</td>
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<td>NDPSC</td>
<td>National Drugs and Poisons Scheduling Committee</td>
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<td>NPS</td>
<td>National Prescribing Service</td>
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<td>OTC</td>
<td>Over-The-Counter</td>
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<td>PBS</td>
<td>Pharmaceutical Benefits Scheme</td>
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<td>Guild</td>
<td>Pharmacy Guild of Australia</td>
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<td>PSA</td>
<td>Pharmaceutical Society of Australia</td>
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<td>QCPP</td>
<td>Quality Care Pharmacy Program</td>
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<td>QUM</td>
<td>Quality Use of Medicines</td>
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<td>RPSGB</td>
<td>Royal Pharmaceutical Society of Great Britain</td>
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<td>SHPA</td>
<td>Society of Hospital Pharmacists of Australia</td>
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<td>SUSDP</td>
<td>Standard for the Uniform Scheduling of Drugs and Poisons</td>
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<td>S2/S3 Standards:</td>
<td>Standards for the Provision of Pharmacist Only and Pharmacy Medicines in Community Pharmacy</td>
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<td>TGA:</td>
<td>Therapeutic Goods Administration</td>
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CHAPTER 1 – INTRODUCTION

1.1 STUDY OVERVIEW

This study is designed to investigate pharmacy practice regulation, and the extent to which community pharmacists incorporate a risk management approach into their expanded practice role. It is set against the changing role of Australian community pharmacists towards the provision of patient care services and an expanding role as medication managers. The study focuses on the increased professional responsibility of pharmacists regarding patient care, and their potential legal liability associated with this evolving role.

The expansion of the pharmacist’s role necessitates accountability and a sharing of responsibility with medical practitioners, for patients’ medication-related needs. However, limited research exists on pharmacists’ potential legal liability within the context of the expanded role and new technologies in Australia. Thus, a need was identified to evaluate pharmacists’ potential liability and to inform the profession of the possible legal and disciplinary consequences. Awareness of such outcomes may assist the profession to develop much-needed risk management procedures.

1.2 BACKGROUND

The practice of pharmacy in Australia has changed over recent years, as in many other countries, from a historical focus on the product to a greater emphasis on the patient and the provision of patient care services. Various factors have contributed to this change in practice. These include the:

- International realisation of the importance of pharmaceutical care and the role of pharmacists in practising pharmaceutical care (Hepler & Strand, 1990);
• Development of a Quality Use of Medicines (QUM) policy framework with the launch of Australia’s National Medicines Policy in 2000 (Department of Health and Ageing, 2002);

• Increased emphasis on evidence-based practice and the awareness of the need for evidence on quality and safety in health care delivery;

• Continuous development of new and complex medicines by the pharmaceutical industry, and the subsequent registration thereof with the Therapeutic Goods Administration (TGA) (Best et al., 2001), requiring that pharmacists be informed about these new therapies in everyday practice functions and when performing medication reviews;

• Increased tendency towards the down-scheduling of prescription medicines to become available as Over-The-Counter (OTC) therapies in Australia as well as in other countries (Blenkinsopp, 2004). The changing regulatory status of these medicines places a responsibility on pharmacists to ensure the appropriateness of the product for a specific patient, and to provide detailed advice and keep records when supplying these medicines to patients or carers;

• Increased support from government towards generic substitution (Lockney, 2003), placing increased responsibility on pharmacists as they need to consider the suitability of a generic product for a specific patient, and to provide relevant information to minimise confusion regarding brand changes (Smith & McLachlan, 2006);

• Shift towards competency-based education and the expanded knowledge-base of entry-level pharmacists regarding patient care services (Pharmaceutical Society of Australia, 2003);

• Development of pharmacy practice standards and guidelines by the profession to define the required level of practice (Pharmaceutical Society of Australia, 2006c);

• Development of medication management review services and the payment of pharmacists by government for medication reviews (Emerson, 2005), creating an opportunity for pharmacists to work closer with prescribers in the management of patients’ medication, and hence the requirement that pharmacists have an increased knowledge of medicines, patients and diseases;
• Increasing pressure on many community pharmacists to balance financial pressures with good practice and professional ethics (Tullett et al., 2003); and
• Changes in consumer behaviour regarding health care services resulting in increased expectations towards health professionals; the shift in decision-making power towards consumers; and the trend to litigate against health professionals (Forrester & Griffiths, 2005).

With the changes in pharmacy practice, pharmacists have pressed for recognition as experts in medicines and to become more involved in the medication management process. The new role has been accepted enthusiastically, and has to some extent been implemented by the pharmacy profession. However, the change of role causes a correlative duty and, as the profession achieves greater recognition, the law will require a higher degree of skill and knowledge.

1.3 PURPOSE OF THE STUDY

This exploratory study focuses on the changing role of community pharmacists, the regulatory framework and the risk management procedures applied in practice to manage professional responsibility and potential legal liability. The aim of the research is to inform the profession of the gaps in risk management within the context of an expanding role.

The objectives of the research are to:

1. Explore instances where a lack of good practice standards and risk management procedures resulted in the pharmacist registrant undergoing disciplinary action by the Pharmacists Board of Queensland;

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1 The Queensland pharmacy registering authority established under the provisions of the Pharmacists Registration Act 2001 (Qld). The functions of the Board are contained in section 12 of the Act and the powers under section 14.
2. Review the evidence and standards of proof used by the Pharmacists Board of Queensland in disciplinary processes;

3. Explore community pharmacists’ awareness of the need to have risk management processes in place, and the resources they used to develop the practice processes;

4. Explore pharmacists’ knowledge of endorsed practice standards and guidelines; and

5. Identify regulatory consistencies and differences amongst Australian jurisdictions that impact on community pharmacy practice.

Figure 1.1 is a flow diagram representing the link between the research objectives and the context of the research:

- The first row (top four boxes) represents the contextual factors that directly impact on risk management in community pharmacy practice: contemporary pharmacy practice has resulted in a change in the role of the pharmacist, which impacts on pharmacists’ professional responsibility and potential legal liability. This, to some extent, is reflected in the regulatory requirements with practice policies and standards supporting the changed role. However, it is not known to what extent pharmacists utilise the endorsed standards, policies and guidelines to develop risk management processes and procedures.

- The three shaded boxes in the middle represent the three sources of data that will be used to inform the researcher of the current risk management practices in community pharmacy.

- The following two rows represent the specific themes that will be focused on to inform the researcher.

All of this information will be used to assess risk management in community pharmacy practice within the context of an expanding role.
Figure 1.1: Flow diagram of research objectives within the practice context.

* The Queensland Health Quality and Complaints Commission (HQCC) is also a potential source of health complaints, specifically those complaints concerning health service providers. However, the Commission was only established on 1 July 2006 under the *Health Quality and Complaints Commission Act 2006* (Qld), replacing the Health Rights Commission. At the time of the data collection for this thesis, the inclusion of HQCC data was considered by the researcher but the Commission was not well established at that stage. However, future research should include the HQCC processes and cases.
1.4 SIGNIFICANCE OF THE STUDY

The identification of how pharmacists adapt and work within their continually expanding practice role is crucial. Adopting a new professional role requires that pharmacists perform the functions associated with the changed role with care. However, it has not yet been established how and by what means the new guidelines, policies and community expectations have been incorporated into the work of the community pharmacist, or the ways in which they are identifying and managing risk.

In the legal context, instances of unintentional or inadvertent dispensing errors, such as giving a patient the wrong medication or the incorrect labelling of medication, are relatively straightforward, as the wrong product or incorrectly labelled product can be used as evidence. Although determining who was at fault is often a complex process, once a mistake has been determined and a pharmacist found to have been negligent, the legal outcome in those areas of pharmacy practice is relatively predictable.

However, new patient care areas of pharmacy practice are less procedural in nature, and often require professional judgement specific to the individual patient’s needs. These intellectual services therefore pose a different challenge in determining a pharmacist’s liability. Case law involving a failure to warn a patient about potential side effects, or the failure to identify a drug-drug or drug-disease interaction, or the failure to detect an overdose, involves a substantial discretionary element and is open to different interpretations in terms of the pharmacist’s duty of care to identify risks and the pharmacist’s liability.

In relation to pharmacists’ duty of care, tort law aims to maintain the quality of health care through the threat of litigation, thereby maintaining and improving the standard of practice and the competence to practise. However, there is a paucity of information in relation to pharmacists’ legal liability regarding their expanded role within the Australian context. The need to do more research regarding the increased legal liability was already recognised in 1997 (Dwyer).
Recent international cases provide a basis for analysing the pharmacist’s duty of care in this area of practice (Christensen et al., 2001; Asbury, 2000), as do cases involving other health professions. These analyses are intended to inform precautionary practices for the pharmacy profession. Additionally, new civil liability legislation, introduced in all states and territories following the Review of the Law of Negligence in 2002, is considered relevant in attempting to determine the potential effect on the practice of pharmacy.

The responsibility of pharmacists in the evolving changes in pharmacy practice towards patient care has yet to be clarified. This study investigates the regulation of the pharmacy profession in Australia to evaluate whether legislation has developed with the changed role. It also investigates how patients’ medication management is enacted by pharmacists within contemporary practice settings. This study aims to use the findings to assist the profession to prepare for its new role(s) through developing strategies to improve and maintain quality and safety, as per the government’s mandate. This includes managing risks to patients and pharmacists. Better information on current practice therefore has the potential to guide future developments, improve the quality of care provided by pharmacists and avoid potential litigation.

Limited research exists regarding pharmacists’ potential legal liability within the context of the evolving role of the pharmacist towards patient care services in Australia. This study therefore aims to contribute significantly to the development of processes to improve risk management procedures, specifically with regard to the provision of newer patient-care services in community pharmacy practice.

1.5 CLARIFICATION OF TERMS

The terminology used in this thesis derives from the professional disciplines of pharmacy and law. As these terms are not widely recognised, they are listed under the Glossary of Terms to guide the reader.
1.6 THESIS STRUCTURE

Chapter One introduces the study and provides an overview of the context and background in which the study was conducted. The significance and purpose of the study are also explained. Chapter Two presents the literature review, identifying and describing the changed role of community pharmacists and the role of practice standards in the context of community pharmacy practice. The role of the pharmacy registering authorities in the regulation of the profession is discussed, with specific reference to the disciplinary function. Developments in professional negligence are highlighted and case law used to explain pharmacists’ potential liability. This is followed by a discussion on medication incidents and the conceptual framework within which the study is situated is explained. Chapter Three identifies and describes the methodological approach to the study. The reasons for situating the study in the interpretive paradigm are discussed and justified, and the methods used to collect and analyse the data outlined. This chapter also provides a description of the ethical considerations underpinning the study and measures taken by the researcher to ensure the rigour and trustworthiness of the findings. Chapter Four presents the results of the research through an analysis of disciplinary cases and semi-structured interviews with pharmacists, and a comparison of interstate pharmacy regulatory requirements. The findings are discussed in Chapter Five as it relates to the regulation of the profession and issues that potentially cause risk in community pharmacy practice. This is followed by a discussion regarding the appropriate utilisation of pharmacy support staff. Chapter Six concludes the thesis with a set of recommendations applicable to pharmacy regulation and practice risk management, as well as implications for future research.
CHAPTER 2 – EMBEDDING THE RESEARCH QUESTION

2.1 INTRODUCTION

The purpose of this chapter is to examine the literature to evaluate the need to improve risk management in community pharmacy practice. This chapter identifies published materials as applicable to pharmacy practice and other health disciplines of relevance to identify gaps in the regulation of the pharmacy profession and risk management strategies.

The chapter begins with an overview of community pharmacy practice in Australia and the framework within which community pharmacy practice has developed. The developments in community pharmacy practice are considered with an emphasis on the changed role of pharmacists, their responsibilities and potential legal liabilities. This information provides an understanding of how the profession has evolved and how these changes potentially impact on risk identification and management.

A discussion of the development of practice standards in Australia emphasises the importance of practice standards in setting the appropriate level of practice. The combined role of the professional organisations and the pharmacy registering authorities with regard to the development of practice standards is discussed. Standards relating to patient care pharmacy services are discussed in detail, and potential risks in the delivering of these services are identified.

An overview of the regulation of the pharmacy profession throughout Australia follows. Issues related to professional practice, professional error and the pharmacist’s duty of care are examined through the use of relevant legislation and case law. The recent developments in Australian civil legislation and experiences from other professional groups are discussed and applied to pharmacists. International case law is considered and predictions made regarding application to Australian pharmacy practice. Queensland legislation is specifically used throughout the discussion to demonstrate application to the practice of pharmacy.
Information about medication incidents is analysed to identify pharmacy practice risk areas. This information is used to inform current community pharmacy risk management practices.

The risk management process and how risk management leads to quality in health care is discussed. The Australian/New Zealand Risk Management Standard (Standards Association of Australia, 2004b) and Donabedian’s framework (Donabedian, 1992) are applied to community pharmacy practice to form a framework for the identification and management of risk.

The chapter finishes with the research questions, which have been formulated following the critical appraisal of the published materials.

### 2.2 PHARMACY PRACTICE CONTEXT

Community pharmacy practice differs in principle from other primary health care providers in that pharmacists have a commodity to trade: pharmacy practice is influenced by the contradictory retailing versus professional activities. At the same time as undertaking a wide range of professional activities, pharmacists in community practice are retailers (Benrimoj & Frommer, 2004). However, as the providers not only of health products but also health services, community pharmacies have a number of important features that distinguish them from other retail businesses, as highlighted by Wilkinson in the National Competition Policy Review of Pharmacy (2000, p. 4):

- Many of the products sold are not ordinary items of commerce and there is considerable discretion in dispensing prescriptions and medicines recommended by pharmacists;
- The medicines sold are capable of causing not only benefit if used properly, but also harm if used improperly; and
- In many cases, there is ‘value added’ in the provision of a product through the advice given by pharmacists to consumers.

Through their central role in supplying prescribed and other medicines, community pharmacies form an important part of Australia’s health care infrastructure and the delivery of medication services (Benrimoj & Frommer,
Community pharmacy in Australia has become a significant source of a wide range of health care services in the community (Albrecht et al., 2006). As registered health professionals, pharmacists have an obligation to exercise reasonable care and skill in the practice of the profession, and be professionally accountable.

Australia has been at the forefront of an international trend towards the incorporation of cognitive services in community pharmacy practice (Gowan & Roller, 2004; Benrimoj & Frommer, 2004), with the emphasis evolving away from the distribution of medicines towards providing and being paid for professional services. Community pharmacy practice has therefore changed significantly over recent years, and it is thus particularly important that pharmacists follow good practice standards and have the necessary risk management processes in place to ensure safe patient care. Failure to take reasonable care in performing professional activities may render pharmacists liable to legal proceedings for breach of professional duty.

The changes in community pharmacy practice in Australia have taken place against a background of government initiatives and developments in Australia’s pharmaceutical policy framework, as well as the medication regulatory framework (Benrimoj & Frommer, 2004). Various national reviews have played a significant role in shaping both the profession and the education of pharmacists. Highly important in the development of community pharmacy are the Pharmaceutical Benefits Scheme (PBS) and the Community Pharmacy Agreements, that determine dispensing fees and those services for which pharmacists have been, and will be, paid for by government. The following sections will expand on these initiatives and programs and the perceived value of the changed role and potential future roles for pharmacists. This will set the scene with regard to pharmacists’ potential legal exposure and the risk management strategies that need to be in place.
THE POLICY FRAMEWORK

Throughout the 1990s, several medication-related policies and strategies impacting on pharmacy practice and pharmacists’ responsibilities were implemented in Australia. This started with the development of the National Medicines Policy to ensure the availability of essential, affordable drugs of acceptable quality, safety and efficacy (Department of Health and Ageing, 2000). A major review in Australia throughout the 1990s subsequently led to the launch of Australia’s National Medicines Policy in 2000. The aim of the Policy was to meet medication and related service needs, in order to achieve both optimal health outcomes and economic objectives. One of the Policy’s four central objectives relates to the Quality Use of Medicines (QUM), which is defined as the judicious, appropriate, safe and effective use of medicines.

Australia’s National Strategy for QUM, released in 2002 to complement the Policy, specifically detailed the range of partnerships and activities to improve the QUM (Department of Health and Ageing, 2002). The Strategy lists the key partners in achieving QUM, which include prescribers and providers of medicines. In fulfilling both these roles, pharmacists are therefore crucial to the achievement of QUM. The Strategy (p. 10) places a specific obligation on community pharmacists, as health practitioners and educators, to:

- Assist people in making informed decisions and learning more about health issues and health care through information, education and discussion;
- Become more aware of the risks and benefits of medicines, the possibility of non-drug options and the importance of a healthy lifestyle;
- Utilise objective information, resources and services to make decisions and take actions that enable medicines, when required, to be chosen and used wisely;
- Continually develop knowledge and skills to use medicines appropriately; and
- Become more aware of the place of medicines within society.

These are broad, non-measurable obligations. There is overall agreement that pharmacists should accept the opportunity as they, as custodians of medicines, are particularly well situated to work both with the other members of the health team and healthcare consumers to promote the implementation of QUM initiatives (Pharmaceutical Society of Australia, 1997). Although various
programs and initiatives have been implemented to promote QUM at community pharmacy level since the launch of the Strategy, it has not been well published to what extent the overall population of community pharmacists have accepted the challenge to actively promote the QUM.

THE MEDICATION REGULATORY FRAMEWORK

As pharmacists are the main suppliers of medicines to consumers, the medication regulatory framework has a significant influence on the practice of pharmacy. A variety of legislative controls are in place to control the everyday handling of medicines. These vary between Australian jurisdictions and the differences complicate the implementation of consistent standards and processes in community pharmacy practice.

The manufacture and supply of medicines in Australia are highly regulated at the federal and state and territory levels. At federal level the regulation is primarily through the Therapeutics Goods Administration (TGA), a division of the Commonwealth Department of Health and Aged Care. All products with therapeutic claims are required to be registered by the TGA. The role of the TGA, through the Therapeutic Goods Act 1989 (Cwlth) and subordinate legislation, is to assess the safety and efficacy of medications proposed to be sold on the Australian market. The TGA also regulates the advertising and labelling of therapeutic goods.

Under the Act, manufacturers are required to provide product information (known as ‘PI’) in relation to medicines made by them and which they are seeking to market in Australia. This information is defined by the Australian Guidelines for the Registration of Drugs as ‘information sufficient to ensure the safe and effective use of the drug under nearly all circumstances’. Section 29A of the Act requires that manufacturers notify the TGA immediately of any adverse information relating to medicines of which they become aware. This information includes unintended harmful effects when used as recommended, and very serious penalties apply for non-compliance. However, pre-registration clinical trials focus on efficacy rather than safety, and the number of patients in
most clinical trials is often limited to a small fraction of the number needed to expose the less common adverse outcomes (National Prescribing Service Limited, 2005). All potential adverse effects are therefore not known at the time a new medicine is registered, and their true incidence often becomes apparent only after the medicine is more widely used in a diverse patient population (National Prescribing Service Limited, 2006).

The reporting of adverse reactions to medicines is therefore an important post-marketing surveillance and safety process. Research conducted over a six-month period found that from 8,215 encounters between general practitioners and patients, 852 patients (10.4%) reported they had experienced an adverse medication reaction during the previous six months (Miller et al., 2006). Although Roughead (2005) indicated that the number of reported adverse medication reactions to the Adverse Drug Reactions Advisory Committee (ADRAC) is increasing, statistics indicate that the reporting of adverse medication reactions is still low, and has to improve (Low, 2005). The low reporting rate can in part be explained by the fact that the reporting of adverse medication reactions is voluntary. The reporting of adverse medication events therefore must be improved by the TGA to ensure the medicines on the market are continuously monitored with regard to safety profiles. Health professionals, and particularly pharmacists, should play an important role in the reporting of adverse medication events.

The TGA’s regulatory approaches are complemented by state and territory controls over who may possess, prescribe, dispense, supply, sell and administer therapeutic goods. The state and territory regulatory control of medications is achieved through a complementary set of poisons (or other) legislation and health practitioner legislation. Table 2.1 lists the poisons legislation in each jurisdiction.

In general, the legislation in the various jurisdictions endorses doctors to prescribe most medicines with very few limitations; veterinary surgeons may prescribe for animals; and dentists may prescribe for dental treatment only. In Queensland, nurse practitioners with specific post-graduate training have
limited prescribing rights under drug therapy protocols (section 175 of the Health (Drugs and Poisons) Regulation 1996). Optometrists with specific postgraduate training had recently been given limited prescribing rights in all of the jurisdictions as well as limited prescribing under the Pharmaceutical Benefits Scheme (Australian Government - Medicare Australia, 2008).

Table 2.1: Sources of drug and poisons legislation.

<table>
<thead>
<tr>
<th><strong>Federal legislation</strong></th>
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<tbody>
<tr>
<td><strong>Therapeutic Goods Act 1989 (Cwlth)</strong></td>
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<td><strong>Narcotic Drugs Act 1967 (Cwlth)</strong></td>
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<td><strong>National Health Act 1953 (Cwlth)</strong></td>
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<th><strong>State and territory legislation</strong></th>
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<tr>
<td><strong>Qld:</strong>  Health Act 1937 (Qld)</td>
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<tr>
<td>Health (Drugs and Poisons) Regulation 1996 (Qld)</td>
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<tr>
<td><strong>ACT:</strong>  Poisons Act 1933 (ACT)</td>
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<tr>
<td>Poisons and Drug Act 1978 (ACT)</td>
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<td>Poisons Regulation 1996 (ACT)</td>
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<tr>
<td><strong>NSW:</strong>  Poisons and Therapeutic Goods Act 1966 (NSW)</td>
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<tr>
<td>Poisons and Therapeutic Goods Regulation 2002 (NSW)</td>
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<tr>
<td><strong>NT:</strong>  Poisons and Dangerous Drugs Act 1983 (NT)</td>
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<td>Poisons Regulations 1975 (NT)</td>
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<td><strong>SA:</strong>  Controlled Substances Act 1984 (SA)</td>
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<td>Controlled Substances (Poisons) Regulation 1996 (SA)</td>
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<td><strong>Tas:</strong>  Poisons Act 1971 (Tas)</td>
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<td>Poisons Regulations 1975 (Tas)</td>
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<td><strong>Vic:</strong>  Drugs, Poisons and Controlled Substances Act 1981 (Vic)</td>
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<td>Drugs, Poisons and Controlled Substances Regulations 2006 (Vic)</td>
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<tr>
<td><strong>WA:</strong>  Poisons Act 1964 (WA)</td>
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<td>Poisons Regulations 1965 (WA)</td>
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The drugs and poisons legislative requirements, as well as those concerning health practitioners, vary between jurisdictions, and a number of the differences impact directly on pharmacy practice, for example: provisions on interstate prescriptions (Beirne, 2006); the prescribing and dispensing of Schedule 8 (S8) medicines; the storage of Schedule 2 (S2) medicines; the record keeping and labelling of Schedule 3 (S3) medicine supplies; and the issuing of medication sample packs. It has, however, not yet been published to what extent the differences in all of these regulatory provisions throughout the jurisdictions impact upon the practice of community pharmacy throughout Australia.

**MEDICINE SCHEDULING**

There is a trend in Australia towards the down-scheduling of certain categories of medicines as they prove to have a relatively safe profile. This increasing tendency to down-schedule medicines not only provides pharmacists with an expanded range of substances available as OTC therapies, but also potentially increases the professional responsibility and subsequently the professional liability risk.

At the federal level the National Drugs and Poisons Scheduling Committee (NDPSC) considers the scheduling and rescheduling of medicines and chemicals for inclusion in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). Although toxicity is one of the factors considered by the NDPSC, the decision to include a substance in a particular Schedule also takes into account other criteria such as the purpose of use, potential for abuse, safety in use and the need for the substance (Health Insurance Commission, 2004). Down-scheduling requests are submitted periodically by pharmaceutical

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2 The National Drugs and Poisons Scheduling Committee (NDPSC) has been established under section 52B of the Therapeutic Goods Act 1989 and consists of state and territory government members and other persons appointed by the Minister such as technical experts and representatives of various sectional interests. Details of the NDPSC are available at <http://www.tga.gov.au/ndpsc/index.htm> Viewed 16 January 2006.
manufacturers as a result of the normal life-cycle of products: as new products enter the market, manufacturers prefer to focus their prescriber marketing efforts on the newer products, encouraging the down-scheduling of established therapies to become available without a prescription (Safe Medication Manufacturers’ Association of South Africa, 2007). The continuous cost increase of the Pharmaceutical Benefits Scheme (PBS), which places a financial burden on the government, potentially plays a role in certain NDPSC down-scheduling decisions as the OTC availability of chronic medicines reduces PBS expenditure.

The tendency for down-scheduling of medicines is also evident in other countries. In the United Kingdom (UK) from 1992 to 2002 there were approximately 50 changes to the legal status of medicines that facilitated easier access by patients. In a UK government document entitled ‘Building on the best’ which was published in February 2004, the UK government committed to doubling the rate of switches from prescription medicines to pharmacy medicine from five to 10 per year (Blenkinsopp, 2004).

Medicines that have been down-scheduled by the NDPSC from Prescription (S4) to Pharmacist Only medicine (S3) during 2004 include the oral preparation for vaginal thrush Diflucan® (fluconazole); the emergency postcoital contraceptive Postinor-2® (levonorgestrel); and the weight management product Xenical® (orlistat). Issues involving pharmacists’ potential risk of legal liability are often raised after the down-scheduling of a product (Dwyer, 2004). This is mainly because when an OTC medicine is requested, it is a requirement that advice on the selection and use should be provided during the supply process, and potential drug-drug or drug-disease interactions should be taken into consideration.

Pharmacists have a legal responsibility to determine the appropriateness of an OTC medicine, specifically of S3 medicine, for the specific patient. Pharmacists also need to provide adequate advice regarding correct usage. The increase in the range of medications available to consumers therefore causes an increased pressure on pharmacists to be available to discuss treatment options and to
provide appropriate advice to patients, as these medicines require careful consideration and professional judgement before being supplied. Pharmacists also need to ensure the provision of advice takes place in an area of the pharmacy that provides appropriate privacy (Pharmaceutical Society of Australia, 2006a).

These scheduling changes clearly demonstrate the increasing need for vigilance by pharmacists and regulatory authorities.

THE EDUCATIONAL CONTEXT

The university training of pharmacists has changed significantly over the last two decades to prepare students sufficiently for the changing role of pharmacists in relation to the provision of primary health care and the increasing emphasis on clinical pharmacy. In the early 1990s it was identified that the traditional three year undergraduate pharmacy training in Australia was insufficient, and after an extensive inquiry in 1992, the House of Representatives Standing Committee on Community Affairs reported on the prescription and supply of drugs, making the following recommendation (In Roller, 1999, p. 557):

In order to provide a stronger comprehensive educational case to equip graduates for the realities of pharmacy practice, the Committee recommends that a four-year undergraduate course in pharmacy be introduced to replace the current three-year undergraduate course and the pre-registration training year.

This recommendation realised the need for a longer period of tertiary education, however it did not take into consideration the importance of the pre-registration year. The Association of Pharmacy Registering Authorities (APRA) therefore passed the following resolution in 1996 (In Roller, 1999, p. 557):

Acknowledging the expanding contribution of pharmacists in health care delivery in Australia, and the consequent need for a more comprehensive undergraduate education program, APRA affirms that a four year degree in pharmacy together with an appropriate period of practice training approved by individual registering authorities be the minimum requirement for initial registration.
At that stage undergraduate pharmacy education in Australia changed in duration (from three to four years), context and level of expertise required to equip students with the necessary level of competence (Roller, 1999). This is also the case in other countries (Wiedenmayer et al., 2006). Griffith University in 2004 was the first Australian university to further extend the minimum tertiary education period to four-and-a-half years. This further increase in length and level of pharmacy training has already been established in the United States of America (USA) and a number of European countries, where pharmacy undergraduate education varies from between five and six years’ duration, and involves varying periods of externships and internships.

University education in Australia has therefore changed to equip students with the required level of competence to provide patient care services. Contemporary education aims to prepare students to provide patient-focused services through problem-based learning, case scenarios and Objective Structured Clinical Evaluation (OSCE) assessments. Students are also increasingly exposed to real-life pharmacy practice through placement programs, which is a mandatory accreditation requirement and forms a significant component of the various pharmacy training programs in Australasia (Chapman, 2003).

In order to be eligible for registration as a pharmacist with the relevant state or territory professional Board, a period of pre-registration training in a pharmacy (consisting of at least 48 weeks in Queensland and similar periods in the other states and territories) must be completed following graduation. During the pre-registration period, pre-registration pharmacists undergo continuous assessment based on the competency standards developed by the Pharmaceutical Society of Australia (PSA). Competency is defined by the PSA as the ‘skills, attitudes and other attributes attained by an individual based on knowledge and experience which together are considered sufficient to enable the individual to practise as a pharmacist’ (Pharmaceutical Society of Australia, 2003, p. 11). The competency standards consist of eight functional areas:

1. Practise pharmacy in a professional and ethical manner
2. Manage work issues and interpersonal relationships in pharmacy practice
3. Promote and contribute to optimal use of medicines
4. Dispense medicines
5. Prepare pharmaceutical products
6. Provide primary health care
7. Provide medicines and health information and education
8. Apply organisational skills in the practice of pharmacy

Four of the eight functional areas relate directly to the provision of patient care services: promote and contribute to optimal use of medicines (3); dispense medicines (4); provide primary health care (6); and, provide medicines and health information and education (7). Functional area (1) covers overall professional and legal aspects; (5) covers the preparation of pharmaceutical products; and areas (2) and (8) focus on management skills. These competency standards are also used by the Australian Pharmacy Council to evaluate, approve and accredit new and existing pharmacy schools and their educational programs.

New registrants are therefore equipped with a wide range of knowledge and skills to provide patient care services. However, they also need practice mentors to guide them in the provision of patient care services. Overseas research has shown that new pharmacy registrants who do not practise patient focused care due to working in pharmacies that are not appropriately set up to enable these services to be delivered, lose their patient care focus within a relatively short time period (Cipolle et al., 1998). Austin has noted that group socialisation theories apply to young pharmacists and influence them to ‘unlearn’ (Austin, 2002, p. 164):

Once they are left alone, or are immersed in a different setting, the values and norms of a different peer group emerge, one that may not be as open to pharmaceutical care. This peer group may be employers concerned with financial optimization, clients who are unaccustomed to a new role for the pharmacist, or allied health professionals who feel threatened by it. Code-switching suggests there is nothing deliberate, malicious, or convincing in this ability to rapidly “unlearn” in a new context; instead, learners are merely adapting themselves to the reality of a new peer group and behaving in a way to optimize their role within it.

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New registrants therefore need pharmacists who practise patient care as role models. However, many community pharmacists have not implemented patient care services (Pharmacy Guild of Australia, 2007). Young pharmacists who work in those pharmacies are thus not given an opportunity to develop and apply patient care, and may subsequently adapt old practices.

**National Reviews Impacting on Practice**

Two national reviews conducted in the late 1990s under the National Competition Policy had, and still have, a significant impact on the profession of pharmacy and the management of community pharmacy practice, and are therefore worth expanded discussion. These were the National Competition Policy Review of Pharmacy and the Review of Drugs, Poisons and Controlled Substances Legislation.

The National Competition Policy Review of Pharmacy (also referred to as the Wilkinson Review) was commissioned in May 1998 after the Council of Australian Governments (COAG) agreed on the necessity for a review of issues relating to pharmacy ownership, the registration of pharmacists and the location of pharmacies. The team, chaired by Warwick Wilkinson, made 19 recommendations most of which dealt with pharmacy ownership and location. Of particular relevance are the three recommendations that covered the registration and re-registration of pharmacists and the role of pharmacy registering authorities (Wilkinson, 2000, p. 5), which can be summarised as follows:

1. With regard to pharmacists re-entering the profession after a non-practising period, it was recommended that regulatory authorities introduce mechanisms to ensure competence before granting registration to practice.
2. In relation to the annual re-registration of pharmacists, it was recommended that jurisdictions explore and implement competency-based mechanisms as part of the re-registration processes. This recommendation was based on the need for continuing education as a prerequisite for ongoing pharmacist registration.
3. Regarding the role of regulatory authorities, it was recommended that the role of the pharmacy registering authorities should be the monitoring of standards and not the setting of standards.
In response to Recommendation 2, and consistent with international pharmacy trends and national trends of other health professions, various pharmacy registering authorities have or are in the process of implementing programs or requirements for pharmacists to commit to lifelong learning and continual quality improvement of their pharmacy practice (Hooper, 2004a). With regard to Recommendation 3, this approach has been followed by the pharmacy registering authorities throughout Australia (Hattingh et al., 2007a). The authorities have endorsed the standards developed by the pharmacy professional organisations. It is, however, arguable whether this approach is in the best interest of patients, as it is the role of the pharmacy registering authorities, and not the professional organisations, to protect the public.

The Review of Drugs, Poisons and Controlled Substances Legislation is also referred to as the Galbally Review after the Chair Rhonda Galbally. The purpose of the Galbally Review was to examine the case for reform of legislative restrictions on competition contained within the legislation and regulations governing drugs, poisons and controlled substances, and the number and range of medicine schedules. Of specific relevance is the recommendation to determine the need for two OTC schedules, namely Schedules 2 and 3 (Galbally, 2001). The continuous status of the two current OTC schedules is therefore being monitored by the National Co-ordinating Committee on Therapeutic Goods (NCCTG), and will be reviewed in 2010. The Review also recommended the development of comprehensive standards to facilitate a risk-based approach to professional intervention in the supply of OTC products to consumers.

The recommendations made by the Wilkinson and Galbally Reviews have impacted on the practice of community pharmacy in Australia. The profession and the pharmacy registering authorities have since begun to address the

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4 The National Co-ordinating Committee on Therapeutic Goods (NCCTG) is a standing committee of the Australian Health Ministers Advisory Committee (AHMAC) and is responsible for taking the action necessary to bring about co-ordination of legislative and administrative controls on therapeutic goods and poisons and to make recommendations to the AHMAC. Details are available at the NCCTG website <http://www.tga.gov.au/docs/html/ncctg.htm> Viewed 15 May 2007
recommendations through the development and endorsement of specific practice standards and programs. The implementation of these recommendations has hence forced the profession to address many issues important to management of risk in community pharmacy practice.

**THE PHARMACEUTICAL BENEFITS SCHEME (PBS)**

As is the case internationally, community pharmacists in Australia provide their professional expertise mostly in the public eye (Caldwell, 2007). They are retailers who provide a range of professional activities (Benrimoj & Frommer, 2004). One of the main income sources for community pharmacists is dispensing fees under the Pharmaceutical Benefits Scheme (PBS). The PBS is regulated by the *National Health (Pharmaceutical Benefits) Regulations 1960* (Cwlth), under the *National Health Act 1953* (Cwlth). This Act relates to the provisions of pharmaceutical, sickness and hospital benefits, and of medical and dental services in Australia.

Community pharmacies are the principal means, under current health service delivery arrangements through the PBS, by which patients are able to access medicines prescribed by medical practitioners. For dispensing a PBS drug, an approved pharmacist receives a mark-up of 10% on the price of the drug to the pharmacist, plus a composite fee for pre-prepared items. Special provisions exist for drugs that cost over $180, and for the dispensing of extemporaneously prepared items (Australian Government - Department of Health and Ageing, 2007).

The government reduces the cost of pharmaceuticals to patients by (Wilkinson, 2000, p. 18):

- Negotiating an agreed price for the medicine with the supplier of the product;
- Controlling the mark-up applied by wholesalers and pharmacists;
- Remunerating pharmacists an amount determined by the Pharmaceutical Benefits Remuneration Tribunal; and
- Subsidising the cost of the product to patients with the level of subsidy linked to the welfare needs of the patient.
According to Sansom (2004), about 75% of all pharmaceuticals (excluding those provided by state-funded institutions) were funded through the PBS in 2004, and the PBS funded about 650 different drugs (in 1600 dosage forms) marketed as nearly 2500 different brands. A continuous concern to the government is the fact that the Australian government's expenditure on the PBS is continuously increasing. Due to this continuous increase, more emphasis has been placed on manufacturers having to demonstrate the cost-effectiveness of drugs they are seeking to have listed in the Schedule of Pharmaceutical Benefits. Further cost containment measures introduced in 2005 included special patient contributions for some PBS medicines, and a 12.5% generic price reduction policy (Health Insurance Commission, 2005).

Another initiative to reduce expenditure on pharmaceuticals is increased government support of the use of generic medicines. Introduced in 1994, generic substitution under the PBS enables pharmacists to supply an interchangeable brand from the one prescribed, provided the prescriber has not disallowed substitution (Lockney, 2003). Generic substitution directly reduces the cost of pharmaceuticals to consumers and indirectly to the government through a benchmark pricing policy. However, generic substitution under the PBS increases pharmacists’ professional responsibility, as they need to advise patients about the substitution in order to reduce confusion (Smith & McLachlan, 2006; Lockney, 2003).

Changes to the PBS have a direct effect on pharmacy practice, from both professional and financial perspectives. PBS compliance requirements have increased over recent years, and PBS dispensing today requires pharmacists to be up-to-date and vigilant regarding a range of complex PBS rules. Although many of the PBS administrative functions can be delegated to pharmacy support staff, compliance with PBS requirements still places additional burdens on pharmacists. Pharmacists therefore need to be innovative in regard to practice processes in order to minimise the time they need to spend on administrative PBS issues. Complying with PBS requirements places an
administrative burden on community pharmacists, which directly impacts on the time they have available to provide patient care.

PROFESSIONAL REMUNERATION

In recent years there has been a shift in focus towards the incorporation of pharmacist professional services, which has been partly driven by opportunities created as a result of the Community Pharmacy Agreements. These agreements are five year co-operative arrangements between the Australian government and the Pharmacy Guild of Australia (Guild) to formalise the Commonwealth price paid to approved pharmacists for providing PBS medicines and other pharmaceutical-related services (Pharmacy Guild of Australia, 2005).

The First Agreement (1991-1995) included pharmacy amalgamation incentives to reduce pharmacy numbers, and a revised dispensing formula that provided for higher professional fees and lower mark-up (Wendy Phillips, 2004). Funding was also obtained for the development and implementation of a quality assurance and professional practice standards program known as the Quality Care Pharmacy Program (QCPP) (Pharmacy Guild of Australia, 2006c).

In order to encourage community pharmacy to contribute to the implementation of QUM policies, over recent years the government has introduced the following funded opportunities as part of Agreements (Wendy Phillips, 2004):

- The Second Agreement (1995-2000) introduced payment for professional services through the introduction of reimbursement for Residential Medication Management Reviews (RMMRs), and pharmacists who supply medications to the patients in a nursing home could claim $100 per bed per year for RMMR services.

- The Third Agreement operated for the period 1 July 2000 to 30 June 2005 (extended to 30 November 2005) and built on the outcomes of the Second Agreement. Responding to emerging needs and
changed priorities, it included funding for incentive payments to encourage pharmacists to:

- use Consumer Medicine Information (CMI) leaflets in daily professional practice. Pharmacists could claim a payment of 10 cents per prescription item from the Health Insurance Commission for ensuring that CMIs were included in medication packaging or for providing such information separately; and
- provide Home Medicine Reviews.

- In addition to these services, the Fourth Agreement, which came into operation in December 2005 and will be in place until June 2010, introduced remuneration for a number of professional service programs to be implemented over the term of the Agreement. These include (Pharmacy Guild of Australia, 2005, p. 2):
  - the provision of compliance devices or packaging systems to community based patients;
  - patient medication profiling service;
  - diabetes medication assistance implementation trial;
  - asthma medication assistance implementation trial;
  - improved counselling for dispensing of the emergency hormonal contraceptive; and
  - communicable disease prevention.

These programs and the associated incentive and remuneration structures represent a conceptual shift at policy level towards the payment for pharmacist professional services. It also creates certain challenges for community pharmacists, including changing their practice to enable delivery of these professional services in a financially sustainable model (Roberts et al., 2004). However, there is a need to identify strategies that will enable the incorporation of these new professional services into everyday practice.

These newer professional services not only provide pharmacists with the opportunity to expand business practices, but also potentially cause an expanded legal liability, thereby increasing the demand on the profession to remain abreast of professional developments. As stated by Coppock (2005, p.
Agreements require significant negotiation between the Guild and the government over extended periods, and many of the details are kept confidential until final sign-off. This process can leave pharmacy owners and pharmacy employees insecure in regard to the financial implications of the new Agreement, and hence the financial viability of community pharmacy. Research in the nursing profession has indicated a direct relationship between organisational climate and needle-stick injuries (Clarke et al., 2002), as well as a relationship between low morale and reduced quality of care (Gilliland, 1997). It is therefore possible that the uncertainty that precedes finalisation of an Agreement can impact directly upon the quality of community pharmacy services.

It is likely that the future of community pharmacy would be influenced substantially by economic factors such as changes in the PBS and the continuation and introduction of financial incentives to provide services through the Community Pharmacy Agreements. The impact of these changes on pharmacists' legal liability is still to be determined, and pharmacists continually need to ensure appropriate risk management processes are in place.

**GENERIC SUBSTITUTION**

The number of generic medicines in Australia is growing, as is the case internationally (Quinlivan, 2005). Generic substitution not only saves the government money through reduced tender prices for PBS listings, but also results in consumer savings through reduced PBS co-payments. The increased dispensing of generic medicines, however, potentially causes increased risk for pharmacists through the medicine selection process (Christensen et al., 2001), as well as through the increased need to discuss the substitution with the patient.
The increased support for the use of generic products is an attempt to contain the growth of the PBS, and generic dispensing and prescribing had been facilitated through various changes, namely the (Lockney, 2003, p. 7):

- Introduction of a Brand Premium Policy (Brand Pricing) in December 1990 to increase price competition between pharmaceutical manufacturers;
- Introduction of generic substitution in 1994, allowing a pharmacist to supply an interchangeable brand in place of the one prescribed under the PBS. Patients need to pay the price difference if they choose the more expensive brand; and
- Amendments to the National Health (Pharmaceutical Benefits) Regulations 1960 (Cwlth) to increase generic prescribing. These changes required, as of February 2003, that computer prescribing programs must default to promote brand substitution for PBS prescriptions.

The responsibility to ensure bioequivalence of generic products in Australia lies with the companies and the Therapeutic Goods Administration (TGA). However, pharmacists have increased responsibility in selecting an appropriate product and in the provision of advice to patients. The National Prescribing Service (NPS) recommends substitution should occur only after consultation with the patient, with their informed consent, and after considering the following (Smith & McLachlan, 2006, p. 1):

- The patient’s ability to understand and manage the change;
- Whether the presence of particular inactive ingredients (e.g. lactose) limits their choice of brands; and
- Whether packaging differences might present problems.

NPS also identified the following points that should be discussed and clarified with patients (p. 1):

- Advise that alternative brands contain the same amount of the same active ingredient and are as effective and safe;

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5 The National Prescribing Service (NPS) is a member-based organisation providing accurate, balanced, evidence-based information and services to health professionals and the community on Quality Use of Medicines (QUM). To achieve this the NPS works in partnership with GPs, pharmacists, specialists, other health professionals, Government, pharmaceutical industry, consumer organisations and the community. NPS is independent, non-profit and funded by the Australian Government Department of Health and Ageing. Details are available at the NPS website <http://www.nps.org.au/index.php?name=front_home.html> Viewed 21 September 2006
• Reassure that all medicines registered in Australia are required to meet the same strict quality standards;
• Explain which medicine the new brand will replace and that the patient should not take both medicines at once;
• Identify and discuss any differences in appearance between the old brand and the new one;
• Provide the active ingredient name and point it out on the packaging and/or Consumer Medicine Information (CMI); and
• Provide the CMI for the new brand.

Generic substitution must be discussed with patients, and therefore places increased demand on pharmacists’ time during dispensing. Legal commentaries in the United States of America (USA) have indeed suggested that courts should more closely examine the pharmacists’ expanded role in selecting an appropriate generic substitute. This is a result of two reported appellate court cases involving drug product selection in which pharmacists were sued for damages (Christensen et al., 2001). 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 plaintiff suffered an adverse reaction and sued against 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.

In these two cases 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 (Christensen et al., 2001).
An in-depth analysis of the theories of potential pharmacist liability and claims of professional negligence had subsequently been undertaken by legal and pharmacy practice experts in the USA (Christensen et al., 2001). 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, namely: (1) negligence; (2) express or implied warranties; or (3) 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 judgement, and hence increased risk of error.

Pharmacists are required to use professional judgement and not supply a generic brand if there is any doubt the generic will cause patient harm, as the patient's health outcome should be the prime consideration in any brand substitution decision. Pharmacists would be placed in a difficult legal position when basing substitution decisions solely on cost. Other issues, such as the potential for patient confusion, must also be considered as well as the appropriateness of non-active ingredients (such as colouring agents) in patients with specific food allergies. The growing generic market and government push towards substitution therefore places increased responsibility on pharmacists, with a subsequent increased risk that must be managed in community pharmacy practice.

THE VALUE OF PHARMACISTS’ CHANGED ROLE

The role of community pharmacists has evolved from mainly counting and pouring to an active role as a gatekeeper in the medication therapy process. Pharmacists now act as ‘learned intermediaries’ between the manufacturer and patient and need to provide patients with balanced information about OTC and
prescribed medicines (Dwyer, 2002, p. 216). In Australia as well as internationally, the emphasis in pharmacy practice has dramatically shifted towards the added value of pharmacists' knowledge in patients' medication management (Posey, 2003; Benrimoj & Frommer, 2004; Kiel, 2005; Dwyer, 2002). The World Health Organisation (WHO) has supported this changed role and has indicated that, over the last 40 years, the pharmacist's role has changed to that of a 'drug therapy manager' (Wiedenmayer et al., 2006 p. 4). However, many pharmacists still find it difficult to integrate cognitive pharmaceutical services into everyday practice, with financial difficulties quoted as a major barrier (Albrecht et al., 2006).

Pharmacists in everyday practice should play a major role in patients' medication management, and monitor patients' medical histories, identify problems with medication therapy, intervene when necessary to prevent harm, and advise patients to decrease the risk of side effects and increase the benefits of medication therapy. These services involve using professional judgement in everyday functions such as the dispensing process and the provision of advice. Community pharmacists are readily accessible, and are often the first health professional consulted for health advice. In general, community pharmacists provide a wide range of services (Emerson et al., 1998). New roles for Australian pharmacists are continuously being investigated, including prescribing of medicines under specific protocols (Bessell et al., 2005), as is the case in the United Kingdom (Burton, 2006).

Pharmacists are perceived as highly reliable advisers on many personal health matters, trustworthy independent purveyors of health care products, and steadfast partners of the medical profession (Benrimoj & Frommer, 2004). Unfortunately, instances of lack of proper advice and services by pharmacists have also been publicised. For example: in a covert study by the consumers’ watchdog in 2004, 58 of 87 pharmacies were rated by the Australian Consumers’ Association as providing ‘poor’ advice (Australian Consumers’ Association, 2004).
A 2002 systematic review of international published literature between 1990 and 2002 focused on the value of professional pharmacist services. The review encompassed more than 70 randomised controlled trials evaluating professional pharmacist services (Roughead et al., 2002). These trials monitored patient outcomes as the end-point, and were conducted within community, outpatient and extended-care settings. The review indicated clear evidence across a number of different settings of the effectiveness of pharmaceutical care services, continuity of care services post-hospital discharge, and pharmacist education services to consumers and health practitioners. However, it is important to keep in mind that these trials did not necessarily represent everyday practice, and that participating pharmacists may have received additional training for study purposes, and were probably more motivated than the average pharmacist to provide the services.

Australian studies have identified the potential benefits of community pharmacist interventions to the improvement of health outcomes, adherence rates, quality of life and lifestyle modification rates in patients with chronic diseases such as asthma, hypertension and type 2 diabetes (Anticevich et al., 2003; Hughes, 2001; Krass et al., 2004). The value of improved collaboration between pharmacists and general practitioners working towards multidisciplinary health services has also been described in various studies (Penrose-Wall et al., 2004; Batterham et al., 2003).

Although the research indicates that there is a definite value in pharmacists participating in expanded patient services, there is a lack of published research regarding the potential legal liability of pharmacists in the provision of these services. It is therefore important that risks be identified in the provision of these services, and that appropriate strategies be put in place to minimise these risks.

Despite the exciting new role for pharmacists and the many opportunities, the profession is in a state of insecurity. This is partly due to the struggle to maintain the monopoly on medication supply and the threat of open ownership (Wilkinson, 2000). There has also been increased government pressure to
reduce expenditure on the PBS, and several of the measures introduced over recent years have directly impacted upon community pharmacy’s financial viability. There is also an increasing number of discount and internet pharmacies (Bernath, 2003), which poses a direct threat to the financial viability of community pharmacy. These issues create enormous pressure on community pharmacists to provide pharmaceutical services within a financially viable model. While practising, pharmacists are continually required to make professional judgements that involve weighing the quality of service and risk management against financial realities.

Additionally, as the profession of pharmacy is gradually transforming towards the provision of patient centred care and services, the expectations of the public are escalating in respect to knowledge, competence and expertise. These expectations drive the changes in the everyday practice of pharmacy and the standards applicable to practice. Implicit in the professional covenant between the pharmacist and the patient is the idea that the pharmacist has certain moral obligations to the patient, specifically to provide patient care. A component of patient care is the provision of medication therapy that will improve the patient’s health or wellbeing. The change in practice towards patient care therefore places increased responsibility on pharmacists to ensure that both prescribed and OTC medicines are appropriate.

**FUTURE ROLES FOR PHARMACISTS**

New roles for pharmacists are evolving. In Australia these new roles are mainly driven by pressures on the health system, the Community Pharmacy Agreements and government policy. For example, payment for the provision of diabetes medication assistance is being trialled as part of the fourth Guild Government Agreement.

Wider prescribing rights for pharmacists have already been introduced in many developing countries, as well as in the United Kingdom (UK), Canada and the USA (Buckley et al., 2006; Emmerton et al., 2005). These prescribing models vary and in some instances pharmacists need to follow strict protocols and may
only supplement what has already been prescribed by a doctor (Emmerton et al., 2005). In other instances, however, pharmacists with specified training may carry out independent prescribing. Pharmacist prescribing models have already been discussed in most Australian jurisdictions and various prescribing models are currently being trialled, including admission prescribing in hospitals and continued prescribing in aged care facilities (Nissen, 2007). However, there is a lack of official publications on this topic.

Concerns have been raised by the medical profession with regard to pharmacist prescribing. These concerns include the lack of pharmacist access to medical records, accountability and compromised patient safety in not separating prescribing and dispensing (Buckley et al., 2006). Although research has shown some pharmacists may be reluctant to take up these new roles (Buckley et al., 2006), many others are enthusiastic about the opportunity to provide these extended services.

It is worth noting that UK legal experts have commented that these new prescribing rights bring new responsibilities, and pharmacists will have to accept a level of legal responsibility similar to that of doctors in cases of prescribing errors (Newdick, 2003). With new rights and responsibilities comes changed legal liability. Therefore, proper risk management procedures must be put in place before new services are offered.

### 2.3 PRACTICE ETHICS, STANDARDS AND GUIDELINES

A profession, as defined by Professions Australia (1997 at http://www.professions.com.au/Homepage.html accessed 3 November 2005), specifically needs to comply with the following attributes in regard to ethical and practice standards:

A profession is a disciplined group of individuals who adhere to ethical standards and hold themselves out as, and are accepted by the public as possessing special knowledge and skills in a widely recognised body of learning derived from research, education and training at a high level, and who are prepared to apply this knowledge and exercise these skills in the interest of others.
It is inherent in the definition of a profession that a code of ethics governs the activities of each profession. Such codes require behaviour and practice beyond the personal moral obligations of an individual. They define and demand high standards of behaviour in respect to the services provided to the public and in dealing with professional colleagues. Further, these codes are enforced by the profession and are acknowledged and accepted by the community.

Like most others, the pharmacy profession has codes of ethics, practice policies, standards and guidelines that express certain values, goals, aspirations and the perceived role within the wider community (Appelby & Wingfield, 2005). They provide the framework to maintain and raise the quality of pharmaceutical services, and should be used to guide pharmacists in everyday practice. The following sections expand on pharmacy ethics and the development of pharmacy practice standards in Australia. Selected practice standards are discussed in detail, and Queensland legislation is used as an example to explain the role of standards with specific reference to the changing role of pharmacists.

**PROFESSIONAL ETHICS**

The changes in pharmacy practice created a changed relationship between the pharmacist and patient, implying greater ethical responsibility from pharmacists and increased expectations of the patient (Chaar et al., 2003). Pharmacists are continually confronted with controversial issues, such as the dispensing of emergency contraception and abortion pills. Both pharmacists and their employees have already been sued overseas for issues that mainly involve moral decisions (Evans, 2007).

Chaar (2006) highlighted that the Pharmaceutical Society of Australia (PSA) Code of Professional Conduct, adapted from the 1997 version of Royal Pharmaceutical Society of Great Britain (RPSGB) Code of Ethics, had not been updated since 1998, and does not reflect the changed emphasis towards the provision of patient care services and the shift towards patient-centered practices. In contrast, the RPSGB Code of Ethics has continuously been updated to keep up with the changing role of pharmacists in the UK (Royal Pharmaceutical Society of Great Britain, 2007). The New Zealand Pharmacy Code of Ethics similarly went through a major revision between 1998 and 2004.
to reflect the practice changes (Pharmaceutical Society of New Zealand, 1998; Pharmacy Council of New Zealand, 2004).

The PSA Code, consisting of nine principles, should form the basis of pharmacists’ activities (Pharmaceutical Society of Australia, 1998). Yet research conducted in 2005 indicated that community pharmacists do not refer to the Code, but rather rely on common sense to circumvent ethical dilemmas in practice (Chaar et al.). A lack of training in professional ethics, resulting in a lack of confidence in decision-making, was identified – an issue that should be addressed by the profession. The study also found that pharmacists who practise in community pharmacy are more likely to experience a dilemma than those working in a hospital environment. This may be attributed to the lack of the broad network, policies and procedures that exist in hospital practice.

The Code should form the basis of pharmacists’ ethical decisions. It is therefore crucial that the Code be updated to reflect current practice. It is also important that pharmacists have sufficient training and knowledge of the Code to assist them in everyday practice decisions. Ethical dilemmas are directly related to risk and potential legal liability, and should therefore be managed appropriately.

**Practice Standards**

The first line of defence in any litigation will require a pharmacist to show that robust operating procedures are in place, and that these are regularly reviewed and updated (Grogan, 2005). These operating procedures must comply with the standard of practice followed by peers. In Australia, the pharmacy registering authorities have delegated the role of setting the standard of practice mostly to the pharmacy professional organisations. It is arguable whether this approach is in the best interest of the public: it is the role of the pharmacy registering authorities to ‘protect public safety by ensuring health care is delivered by pharmacists in a professional, safe and competent manner’ (Council of Pharmacy Registering Authorities, 2006a). Conversely, the role of the professional organisations is to represent its membership (Pharmaceutical
Society of Australia, 2006b; Pharmacy Guild of Australia, 2006a; Society of Hospital Pharmacists of Australia, 2006). Accordingly, the authorities act in the best interest of the public, while the professional organisations represent the interests of the profession.

The three main pharmacy professional organisations in Australia, namely the 6Pharmaceutical Society of Australia (PSA), the 7Pharmacy Guild of Australia (the Guild) and the 8Society of Hospital Pharmacists of Australia (SHPA), assume a significant role in developing practice standards and guidelines. The development of the standards and guidelines originally followed the 1993 International Pharmaceutical Federation (FIP) recommendation that individual countries had to develop a nationally-recognised, comprehensive set of standards for professional pharmacy practice (International Pharmaceutical Federation).

The standards and guidelines are intended to be used as tools to achieve consistency and uniformity in service delivery and to implement continuous quality improvement to reduce the risk of misadventure (Pharmaceutical Society of Australia, 2006a). The standards specifically applicable to community pharmacy practice are the:

1. Professional Practice Standards, which consist of 17 individual standards, covering both core professional services such as dispensing and counselling, as well as selected specialty standards such as specialised drug information services; and

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6 The Pharmaceutical Society of Australia (PSA) is the national professional organisation for all pharmacists in Australia. Details are available at the PSA website <http://www.psa.org.au> Viewed 21 September 2006

7 The Pharmacy Guild of Australia (the Guild) is an employers’ organisation and is registered under the federal Workforce Relations Act 1996. Its members are owners of community pharmacies throughout Australia. Details are available at the Guild website <http://www.guild.org.au> Viewed 21 September 2006

8 The Society of Hospital Pharmacists of Australia (SHPA) is the professional pharmacy organisation with an especially strong base of members practising in hospitals and other facilities. Details are available at the SHPA website <http://www.shpa.org.au/docs/about.html> Viewed 21 September 2006
2. Standards for the provision of Pharmacist Only and Pharmacy medicines in community pharmacy (S2/S3 Standards).

The Dispensing Standard and extracts of the S2/S3 Standards are attached to provide the reader with some insight regarding the scope of the standards (Appendix 1).

Recent research by Benrimoj (2005) on the supply of S2 and S3 medicines noted the extent to which community pharmacists incorporated the S2/S3 Standards in everyday practice. The outcome of the research was subsequently used in the redevelopment of the S2/S3 Standards in 2005. The Professional Practice Standards similarly underwent a major national review in 2005 that took into consideration an increased consumer focus, changes to pharmacists’ roles, Safety and Quality Council recommendations and risk management processes in the medication management cycle (Pharmaceutical Society of Australia, 2005a; Grogan, 2005). However, similar to the previous version, the new standards appear to be overly complicated and not straightforward (Pharmaceutical Society of Australia, 2006c), and hence are difficult to implement in practice. Additionally, there still is a large degree of overlap between certain standards, as was the case with the previous edition. There is also no research to measure how well the Professional Practice Standards have been implemented and are being utilised in practice.

Although there is a separation in roles between the pharmacy registering authorities and the professional organisations in Australia, the authorities have endorsed the standards developed by the professional organisations, and use them as a benchmark during disciplinary proceedings (Hattingh et al., 2007b). The roles have therefore merged with regard to standard setting, as the authorities use the standards (and, to some extent, monitor the application of the standards), while the professional organisations have the role of developing the standards, in accordance with the Wilkinson Review Recommendations. However, it is debatable whether this approach is in the best interest of the public, as it is the role of the professional organisations to serve their
membership, and not to protect the public, which is the mandate of the pharmacy registering authorities.

The standards and guidelines do not cover legislative requirements, and by themselves are not legally binding. However, in Queensland, through the process of endorsement by the Pharmacists Board of Queensland (Pharmacists Board of Queensland, 2004), the standards and guidelines are legally binding. In accordance with section 374 of the *Health Practitioners (Professional Standards) Act 1999* (Qld), the Board uses them as admissible evidence in disciplinary proceedings.

The question is whether it is appropriate to use the standards and guidelines in disciplinary proceedings if the original intention was for the standards to not be legally binding. Also, the standards and guidelines do not distinguish between services or actions that are absolutely essential. That is, the ‘must-do’ actions intended to provide safe pharmaceutical services are not distinguished from the ‘nice-to-do’ or desirable actions intended to provide a good quality service. Therefore, pharmacists need to use their experience and personal judgement in determining which functions are required to provide the minimum service level to provide safe patient care. As many of these actions relate to practice processes and procedures, the extent of the implementation of the standards significantly impacts on pharmacists’ risk management procedures.

**DISPENSING OF PRESCRIPTIONS**

The PSA dispensing standard is defined as (Pharmaceutical Society of Australia, 2006a, p. 456):

> The pharmacist ensures that dispensing occurs accurately, reflects the prescriber’s intentions, and is consistent with the needs and safety of the consumer.

According to a USA workforce study dispensing remains community pharmacists’ primary function and in the USA the amount of time devoted to dispensing had not changed significantly between 2002 and 2004 (Kreling *et al.*, 2006). This would also apply to Australian community pharmacy and
Dispensing is therefore the core service provided by community pharmacists. Dispensing has developed over years from a mainly technical function to a complex process involving many cognitive aspects. Current criteria require the pharmacist to take into account all relevant information such as ‘other medication the patient is taking, disease states and allergies’ (Pharmaceutical Society of Australia, 2006a, p. 456). Accordingly, the term dispensing in the Australian context includes the patient-centred care aspects that require a pharmacist’s expert knowledge to interpret and evaluate the patient’s medication needs.

The changed definition of dispensing places a responsibility on pharmacists to ensure the prescribed medication is appropriate for the specific patient. This role is particularly important as patients may consult several prescribers in different disciplines and receive prescriptions from each with medicines that may interact and expose patients to potentially serious adverse effects. Pharmacists should therefore play an important role in the overall management of patients’ medication.

The dispensing process comprises both cognitive and technical functions. Cognitive dispensing functions mainly involve those functions that require a pharmacist’s clinical interpretation of the prescription and the provision of advice to the patient or carer. The technical functions include the selection and labelling of the medication, and pharmacists often delegate these tasks to appropriately trained pharmacy support staff (Goodman, 2006a), referred to as dispensary assistants. To fulfil both the professional and legal requirements, the pharmacist must undertake a clinical check of the prescription before handing it to the support staff to ensure the prescribed medication is appropriate. Pharmacists should also be available to intervene in the dispensing process, and are legally required to undertake the final check of the dispensed medicine.

In the legal context, instances of unintentional or inadvertent technical dispensing errors in pharmacy practice are relatively straightforward. In the case of selection or labelling errors, the product itself can be used as evidence.
in cases of liability or unsatisfactory professional conduct. Although it is often a complex process to determine who was at fault, once a mistake has been identified and a pharmacist found to have been negligent or guilty of unsatisfactory professional conduct, the legal outcome is relatively predictable.

Conversely, with the expanded areas of pharmacy practice such as the identification of an interaction or the giving of advice regarding potential side effects of medication, there is greater scope for error. These activities are less task-oriented, and often require professional judgement specific to the individual patient’s needs (Dwyer, 2003; Sweet et al., 2004). These higher cognitive functions therefore pose a different challenge in determining a pharmacist’s liability. For example: cases involving a failure to identify clinically significant medication interactions or medication-disease interactions, or failure to detect an overdose, have a substantial discretionary element.

In 2002, the New South Wales coroner made specific comments about the 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 (Pharmacy Board of New South Wales, 2003b, p. 22):

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.
Pharmacists have a responsibility to interpret and evaluate prescriptions. They should act as a safeguard for prescribers, and therefore the legal separation in the prescribing and dispensing functions. Professional judgement must often be used in the dispensing process.

The pharmacist’s potential responsibility regarding the more cognitive functions may be open to varied interpretations of the standard of care and the identification of risks, especially as there is still only limited information regarding legal precedent. Therefore, pharmacists should develop and implement processes and procedures to ensure dispensing is always undertaken with a structured approach to reduce the risk of error. There is, however, limited research regarding dispensing processes and workflow in community pharmacy practice in Australia. It is not known to what extent pharmacists utilise dispensary assistants to free themselves up to focus on cognitive functions and patient care services.

**THE PROVISION OF MEDICATION ADVICE**

The provision of pharmacist advice is also referred to as counselling, which is defined by the PSA as (Pharmaceutical Society of Australia, 2006a, p. 462):

> The pharmacist ensures that the consumer has sufficient knowledge of their medicines and therapeutic devices to facilitate their safe and effective use.

The following criteria need to be complied with:

1. All consumers are offered counselling by a pharmacist;
2. Counselling is provided according to the needs of the consumers;
3. The most appropriately trained person undertakes the counselling;
4. Written information is used, when available, to supplement oral counselling;
5. The use of therapeutic devices is adequately explained and/or demonstrated to the consumer;
6. The pharmacist systematically records counselling events that they consider clinically important; and

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9 The criteria specify that staff should know that a pharmacist should counsel consumers regarding prescription and Pharmacist Only Medicines.
7. The pharmacist provides counselling that is supported by evidence-based information.

The advisory role of pharmacists, involving both OTC therapies and prescription medicines, has increased with the changes in pharmacy practice. Being accessible, community pharmacists are often the first health professional to be approached by patients. Also, patients on chronic medication need to have their prescriptions filled on a regular, often monthly basis, and therefore patients often have more contact with their pharmacist than with their doctor. This makes a pharmacist’s role in disseminating medication information crucial (Dwyer, 1999).

Pharmacists have a legal and professional obligation to ensure patients have the information they need to enable them to make informed decisions about their medicines. However, the provision of information may not be necessary each time a product is supplied or dispensed. Pharmacists therefore need to apply professional judgement regarding the individual needs of the patients or carers as this, in a significant way, should influence the scope of the advice and how the counselling is conducted, as well as the supportive tools to be used (Low, 2004).

According to Low (2004), appropriate counselling of patients or carers not only provides an opportunity to promote the quality use of medicines, but also provides pharmacists with the opportunity to undertake a final check of the dispensed medicine. The provision of advice thereby fulfils an important risk management activity.

A 2004 review of 51 investigations involving dispensing errors undertaken by the Pharmacists Board of Queensland found that in all but one case, counselling had not been provided by the pharmacist (Low). Similarly, the Pharmacy Board of New South Wales, in investigating more than 6000 complaints over ten years, estimated that, had the patient been counselled, at least 25% of medication errors might have been detected before handing out the medication (Pharmacy Board of New South Wales, 2003a). However, both the Queensland and New South Wales Boards indicated that they accept there
is little need for counselling to be provided on every occasion a prescription is dispensed, and that pharmacists need to use professional judgement.

In the case where a pharmacist has not counselled a patient or carer and the patient suffers a medication adverse event, it would be reasonable in a disciplinary investigation to establish whether the lack of counselling is professional conduct ‘of a lesser standard than those expected’, or whether the pharmacist’s conduct demonstrates a lack of judgement or care (Low, 2004, p. 6). 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 (Brand, 2005).

The expanding role of pharmacists requires that they provide appropriate advice to patients about medicines. The advice should be tailored to each individual patient, and hence requires professional judgement on the part of the pharmacist. Pharmacists should hence have risk management practices in place to help them determine which patients are at most risk of medication incidents, so they can focus on those patients for the provision of advice and information. However, there is a dearth of information about how often pharmacists do provide advice, and to what extent they comply with this new role.

**THE SUPPLY OF PHARMACIST ONLY AND PHARMACY MEDICINES**

Under legislation, pharmacists may supply Pharmacy medicines (S2 medicines) and Pharmacist Only medicines (S3 medicines) without prescriptions. There are six S2/S3 Standards (Pharmaceutical Society of Australia, 2006a, pp. 492-496):

1. The pharmacy has adequate resources to consistently promote the quality use of Pharmacy medicines and Pharmacist Only medicines.
2. All staff members who supply Pharmacy medicines and Pharmacist Only medicines receive initial and ongoing training on products, services, and procedures relevant to their supply.
3. Pharmacy medicines and Pharmacist Only medicines are located in areas of the pharmacy that indicate that they are not normal items of commerce, and are consistent with scheduling classifications.

4. Consumers receive care and advice, appropriate to their presentation and need, that will facilitate the quality use of Pharmacy medicines and Pharmacist Only medicines.

5. The pharmacy documents the provision of Pharmacist Only medicines to ensure quality of care and enhance optimal health outcomes.

6. All staff members respect the rights and needs of all consumers.

It is a core function of pharmacists to assist patients in the management of minor, self-limiting conditions. By making these medicines available without prescriptions, the legislature and the public have determined that the pharmacist, as the learned intermediary, can supply these products, but should provide advice and information to ensure their appropriate use. Pharmacists therefore have a responsibility and a duty of care to ensure the appropriate supply of S2 and S3 medicines.

Section 277 of the Health (Drugs and Poisons) Regulation 1996 (Qld) specifies the requirements for selling a Schedule 3 medicine on request:

278 Sale of S3 poisons

(1) A pharmacist or a person who is approved to dispense a poison under a pharmacist’s direction and supervision, (the seller) must not sell an S3 poison unless -

   (a) For S3 pseudoephedrine-
      (i) the seller is reasonably satisfied the purchaser has a therapeutic need for the S3 pseudoephedrine; and
      (ii) the seller does not know the identity of the purchaser-the purchaser gives the seller an acceptable form of identification; or
   
   (b) for another S3 poison-the seller is reasonably satisfied-
      (i) the purchaser has a therapeutic need for the poison; and
      (ii) of the purchaser’s identity.

(2) The seller must give the purchaser advice on the dosage, frequency of administration, general toxicity, adverse effects, contraindications and precautions to be observed in using the poison.

Pharmacists are therefore required to determine the patient’s identity, to determine and discuss the patient’s therapeutic need for the medicine, and to advise the patient or carer about the correct usage, contraindications, adverse effects and precautions. Sub-sections 277(3), (4), (5) and (6) specify that
pharmacists are required to label the medicine, and that specific information must be on the label. Similar legislation regarding the supply of S3 medicines is in place in the other states and territories. Pharmacists are therefore legally obliged both to ensure the product is suitable for the patient, and to provide adequate advice.

Unfortunately, the profession is often criticised for not providing proper advice in the supply of S2 and S3 medicines (Australian Consumers’ Association, 2004). An analysis of 78 disciplinary cases against pharmacists over a 12-year period in New South Wales found that 48 of the complaints related to inappropriate or illegal supply of particular medicines (Kiel, 2005). Of specific concern was the inappropriate supply of large quantities of S2 or S3 ‘cold and flu’ preparations with pseudoephedrine, which is commonly used for the illicit manufacture of amphetamines. The inappropriate supply of pseudoephedrine-containing products increasingly also became problematic in other states and territories (Gould, 2006). In an attempt to prevent the ongoing illicit manufacture of amphetamines from pseudoephedrine, in October 2005 the National Drugs and Poisons Scheduling Committee recommended changes to the scheduling of all pseudoephedrine products to either S3 when in small quantities (1 January 2006 implementation) or to S4 in bigger quantities (1 April 2006 implementation) (National Drugs and Poisons Schedule Committee, 2005).

The S2/S3 Standards were designed to assist pharmacists meet the legal obligations and the duty of care to consumers. The standards also address the role that appropriately trained pharmacy support staff can play in the provision of these services. Various pharmacy tools have been developed with the S2/S3 Standards to assist community pharmacy practices. These tools include the ‘What-Stop-Go’ and the ‘Carer’ protocols that require pharmacy support staff to use a range of questions to identify when the patient should instead be referred to a pharmacist (Pharmaceutical Society of Australia, 2005b). However, it is not known how well pharmacists have implemented the S2/S3 Standards, and exactly which tools and resources they use in practice or the processes they have implemented in the supply of OTC products.
The Guild has developed a Mystery Shopper Program to assist pharmacists in monitoring how effectively pharmacy support staff use these protocols in the supply of OTC medicines and refer patients to a pharmacist when required. The outcomes of the visits and assessments are then discussed with the applicable pharmacists. However, the outcomes of the Mystery Shopper Program visits and assessments of pharmacies’ performance are not published in pharmacy literature; accordingly the program is not used to train and educate the profession collectively.

**MEDICATION REVIEWS**

The PSA has developed two standards for medication reviews (Pharmaceutical Society of Australia, 2006a, pp. 451 & 452):

- **Comprehensive Medication Review:**
  The pharmacist systematically reviews and evaluates the consumer’s medication treatment regimen and takes appropriate action to optimise therapeutic outcomes and ensure their access to regular reviews.

- **Home Medicines Review (HMR):**
  The pharmacist works with the consumer, general practitioner and other members of the health care team to provide the therapeutic information and advice required to promote optimal therapeutic outcomes for the consumer, effective use and management of medicines and devices by the consumer, and quality use of medicines.

The PSA standards provide the basis of pharmacists’ responsibilities in the medication management process. The medication management review process was formalised in Australia as a follow-up to the international movement in the 1990s towards the provision of pharmaceutical care. The provision of pharmaceutical care was a paradigm shift in the practice of pharmacy which emerged in the mid-1970’s and was extensively researched.

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10 The Mystery Shopper Program is also known as the Standards Maintenance Assessment (SMA) visits. These visits, during which an assessor poses as a customer to request an S2/S3 medicine, are designed to ensure that the S2/S3 Standards are being applied effectively and consistently, and applies to QCPP accredited pharmacies. According to the Quality Care Pharmacy Support centre, all accredited pharmacies can expect to receive at least one SMA visit per year (National Co-ordinating Committee on Therapeutic Goods (NCCTG), 2005).
and promoted by academics in the United States of America in the 1990’s (Hepler & Strand, 1990). Pharmaceutical care can be defined as ‘a practice in which the practitioner takes responsibility for a patient’s drug-related needs, and is held accountable for this commitment’ (Cipolle et al., 1998 p. 13).

Research by Miller et al. (2006) regarding all adverse events reported to general practitioners indicated that 10.4% of practitioners had managed an adverse medicine event during the previous six months. It was estimated in the Quality in Australian Health Care Study that 43% of hospital adverse events were potentially preventable, and that 10% of these adverse events were classified as an adverse drug event (Wilson et al., 1995). Day et al commented on these results (1995), indicating that pharmacists could play an important role in the detection and prevention of adverse medication events. Conducting medication reviews is one of the tools available to pharmacists to assist in identifying potential medication related problems (Roughead et al., 2004).

Medication reviews involve accredited pharmacists making recommendations to general practitioners regarding patients’ medication management. The process not only provides commercial and professional opportunities, but also creates new responsibilities that require definition and standardisation at a national level. The introduction of government remuneration for pharmacists for the provision of medication reviews was not only a significant step towards recognising the role of the pharmacist in the medication management process, but also imposed greater professional obligations on, and thereby potential risks, for pharmacists.

Significant duties and responsibilities are imposed on both community pharmacists and accredited pharmacists in providing medication review services. The Pharmaceutical Defence Limited (PDL) identified potential risk areas in the provision of HMR services, indicating ways in which a pharmacist may be deficient during the HMR process (Pharmaceutical Defence Limited Annual Report, 2004a, p. 12):

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

Participation by the pharmacist in the activity results in increased responsibility and the potential for professional liability on accredited pharmacists. Baker (2006, pp. 17 & 22) reported that litigation involving HMRs had already been filed by mid-2006 and summarised three of the cases:

1. One case emphasised the need for pharmacists to be careful in the manner in which patients’ individual traits and potential addictions are reported.
2. Another case involved failure by the pharmacist to identify a drug-drug interaction and the patient subsequently suffered an adverse effect.
3. A third case involved a general practitioner being sued by the estate of a deceased patient for not implementing the accredited pharmacist’s recommendations and 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 the accredited pharmacist’s recommendations.

Medication reviews involving pharmacists in a community or primary care environment is a relatively new service area in Australia. To date there have been a few cases reported to Guild Insurance (Baker, 2006) that settled out of court. There is therefore a lack of available information regarding the legal liability of the various role-players, namely community pharmacists, accredited pharmacists and general practitioners. The applicable standard of care has not as yet been well defined, and it is therefore particularly important that pharmacists follow recommended timeframes and protocols.

It is assumed that the practice standards, as discussed, represent the agreed minimum standard of practice as the standards are developed by the profession. Practice standards should play an important role in guiding everyday practice, and should be used by pharmacists to develop processes and procedures. It is indeed a characteristic of a professional to adhere to a code of professional conduct and practice standards. Subsequently, another characteristic of a professional, namely to operate within a regulatory framework (Tito, 1994), will be explored.
2.4 PHARMACY REGULATION

Regulation of the pharmacy profession is the principal means of ensuring public trust and confidence in the services pharmacists provide. Various legal pathways can be used by customers of pharmacy services who allegedly suffer injury from an action or omission by a pharmacist to assess and investigate the complaint about their health care (Forrester, 2003, p. 2). These include:

1. Accessing the internal complaints mechanisms of the institution or the private provider;
2. Lodging a complaint with the relevant pharmacy registering authority;
3. Lodging a complaint with the independent statutory complaints unit or commission established in each of the states or territories, for example, the Health Quality and Complaints Commission in Queensland in terms of section 48(2) of the Health Practitioners (Professional Standards) Act 1999 (Qld); and/or
4. Initiating action through the adversarial court system, for example, a claim in professional negligence.

More than one of these processes can be followed simultaneously. The profession itself is regulated through the legislation under which the pharmacy registering authorities operate. The disciplinary outcomes of the registering authorities assist in predicting which sanctions will be imposed in professional misconduct cases. The outcomes of civil litigation through the courts also play an important role in the regulation of pharmacists, as is the case with all health professionals. The following sections will expand on the regulation of the profession in Australia through these mechanisms, and will also explore some international trends to help predict pharmacists’ potential legal liability.

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AUSTRALIAN PHARMACY REGULATION

The regulation of the pharmacy profession in Australia dates back many years, with chemists and druggists establishing colonially-organised Pharmaceutical Societies in the nineteenth century (Haines, 1988). Each new society was modelled on the Royal Pharmaceutical Society of Great Britain (RPSGB), and these colonial societies became powerful influences and important moulders of Australian pharmacy (Haines, 1988). The societies presented the first written expressions of organised standards in education, qualifications and ethics, and also maintained the first schools of pharmacy in Australia (Haines, 1988). They also influenced the development of the first pharmacy act in each colony or state.

Victoria and New South Wales were the first jurisdictions to introduce Pharmacy Boards separate from the then Society Councils in 1876 (Haines, 1988; Bomford & Newgreen, 2005). The separation of roles was a departure from English precedent, where the RPSGB had the authority to maintain the register, conduct examinations, and to discipline pharmacists. The creation of separate bodies distinct from the professional organisations was intended to keep the Boards independent of the organisations and to clearly establish that the Board existed for the public good, whereas the Society acted for the profession. This approach was to be followed by all other states, except for Western Australia. The process to separate the roles in Western Australia has now also commenced through the drafting of the Pharmacists Bill 2006 (WA).

Today, state and territory legislation provides for the regulation of the profession throughout Australia by pharmacy registering authorities that act as authorities for the protection of the public. Therefore, except for Western Australia, there is a separation of roles between the authorities, acting in the interests of consumers, and the professional organisations, acting in the interests of its members (Hooper, 2004b).

The Australian pharmacy registering authorities are entrusted with the regulation of the profession of pharmacy, and have responsibility for the
registration and discipline of registered pharmacists. The role of the authorities is to protect patients. In contrast, the professional organisations represent their members. However, what is in the interest of the public is often also in the interest of the profession. Accordingly, the roles of the registering authorities and the professional organisations overlap, and although there is a separation of roles, a degree of co-regulation exists between the authorities and the professional organisations.

The overlap in functions is specifically evident with regard to practice standards: the professional organisations determine the standard of practice through the development of practice standards, which are used as a frame of reference by the authorities in disciplinary cases. It can be argued as to whether this approach is in the public interest, as the practice standards are developed by the profession with the intention that these standards will guide everyday practice. The standards are therefore not specifically developed for use in disciplinary investigations and actions, and do not have any legal standing unless adopted or endorsed by the authorities.

The main objective of the state and territory legislation relates to the need to ensure QUM in the community by requiring that the supply of medicines is undertaken by appropriately qualified and competent professionals. The authorities have the ability to investigate allegations or suspicions of misconduct by registered pharmacists, and to take disciplinary action as they see fit. In the case of a pharmacist’s registration being cancelled or suspended by a registering authority due to improper professional conduct, authorities in other jurisdictions, whether interstate or overseas, may give effect to that order.

The structures within which the authorities operate differ between jurisdictions. Although there are similarities between the legislative provisions and the powers of the individual authorities, there are various inconsistencies that impact upon the day-to-day practice of pharmacy. For example: the use of dispensing barcode scanners is not compulsory in all states (Guild Insurance/Guildwatch, 2006). The use of barcode scanners has been identified in significantly reducing dispensing errors (Guild Insurance/Guildwatch, 2006),
and this inconsistency therefore creates differences in risk management procedures between states and territories.

In an attempt to *inter alia* harmonise procedures and facilitate communications between pharmacy registering authorities, the Association of Pharmacy Registering Authorities (APRA) was formed in the early 1990s and succeeded in 2002 by COPRA (Council of Pharmacy Registering Authorities, 2004), which was renamed the Australian Pharmacy Council in July 2007. However, many of the legislative requirements still vary significantly between states and territories. The Australian Pharmacy Council, through the New Zealand and Australian Pharmacy Schools Accreditation Committee (NAPSAC), also accredits pharmacy schools to ensure national consistency of university pharmacy courses.

An USA study involving 306 community pharmacies in eight states indicated that the advice provided to patients by pharmacists regarding dispensed medicines varied significantly according to the intensity of a state’s counselling regulation (Svarstad *et al.*, 2004). The study showed a frequency variation between 40% and 94%, which correlated with increasing stringent counselling regulations. The study also indicated that regulations were more likely to be followed if the regulations had been in effect for a longer period. The researcher gave three reasons for the higher rates of counselling under more stringent regulations in effect to a longer period, namely (p. 27):

1. The more stringent regulations set clearer and higher standards, expectations, norms and behaviour. There is more certainty about who should be counselled and who should perform this counselling;
2. Regulations that are longer in duration are likely to be more effective because students and practitioners have had a greater opportunity to learn new counselling standards. Pharmacy educators, professional associations, and employers all have a greater opportunity to develop effective policies, procedures, and training programmes for personnel; and
3. Regulators have a greater opportunity to develop and apply more effective systems of monitoring and enforcement.

No similar research has been published in Australia, so it is not known to what extent the regulatory differences between jurisdictions influence the way
pharmacy is practised throughout Australia. These differences potentially affect risk management procedures implemented and followed by pharmacists.

The Australian model of the separation between the professional regulatory and the professional representation roles had been adopted by New Zealand (Bellingham, 2006), and the UK system is currently undergoing reform to also implement this model (Thompson, 2007).

**NEW ZEALAND AND UNITED KINGDOM PHARMACY REGULATION**

The Pharmaceutical Society of New Zealand (PSNZ) had a dual role until September 2004 when the *Health Practitioners’ Competency Act 2003* (NZ) came into force. This Act put an end to self-regulation of health professionals. The PSNZ was subsequently divided into the Pharmacy Council of New Zealand to regulate pharmacy, and the PSNZ (Inc) for the representative and professional roles. Bellingham indicated a clear distinction between the roles (2006, p. 509); namely, the Council’s roles are to:

- Register pharmacists;
- Ensure pharmacists are fit to practise;
- Set standards for pharmacy education and competence; and
- Protect the public.

whereas the PSNZ (Inc) roles are to:

- Provide professional advice and support;
- Develop practice standards;
- Provide education and training; and
- Represent the interests of pharmacy to government and other organisations.

The decision to split the regulatory and professional representation roles followed two cases of poor practice in medicine that prompted the health minister to initiate the drafting of the Act (Bellingham, 2004). At that stage the New Zealand Government realised the conflict of interest in the self-regulation of professionals. Mandatory continuous professional development for health professionals was also introduced as part of the change. Disciplinary issues
are now being dealt with by the Pharmacy Council where these relate to a competency issue; all other disciplinary issues are referred to the Health Practitioners Disciplinary Tribunal, which deals with disciplinary issues involving all health professionals (Bellingham, 2006). The Tribunal is chaired by a barrister, has three lay members and three members of the relevant health profession.

In the UK, the RPSGB simultaneously has the role of registration, inspection and discipline of its members (Wingfield, 2002; Tullett et al., 2003). This dual role is almost unique amongst other UK health professions (Tullett et al., 2003) and has been criticised by various commentaries (Anderson, 2002; Brown, 2006). As stated by Noyce (2002, p. 650): 'the same body cannot act in judgement and defence of an individual litigant'. The UK system is currently being reviewed as a result of the Foster Review and the passing of the *Health Act 1999* (UK), which provided powers in section 60 to change the regulation of health professions and to amend the National Health System (Appelby & Wingfield, 2005). The changes had been incorporated into a Pharmacists and Pharmacy Technicians Order that will replace the *Pharmacy Act 1954*. The regulatory role of the RPSGB will be taken over by a General Pharmaceutical Council within the near future (Thompson, 2007; Agomo, 2007). The role of the new Council will be to register and regulate pharmacists, pharmacy technicians and premises (Pharmaceutical Journal, 2007).

**AUSTRALIAN PHARMACY DISCIPLINARY DECISIONS**

The pharmacy registering authorities operate under legislative parameters. One of the main functions of the authorities, as mandated by the legislation, is their disciplinary role. Pharmacy errors can have serious consequences, as illustrated by the following outcome:

On the 9th of June Sarah Alder, who was approximately 2 and a half years, died when she ingested the contents of the methadone that was given to Phillips by the Registrant. As I say it is graphic illustration of the need for people who administer dangerous drugs to be scrupulous, not only in their record keeping, but in the procedures that are followed in issuing such medicine. Otherwise tragic consequences such as this can follow. (Matter of John Allison Shay &
Therefore, it is important that the public has confidence that disciplinary outcomes are reflective of the gravity and type of the breach, and are consistent and transparent. A number of pharmacy practice cases have been appealed to the supreme courts following the imposition of sanctions by the Pharmacy Boards of Victoria and Tasmania. However, in all of the cases the courts upheld the Boards’ decisions in regard to the pharmacists’ conduct.

The Supreme Court of Victoria in *Mercer v Pharmacy Board of Victoria* [1968] VR 72 and *Loewy v Pharmacy Board of Victoria* [1991] VSC 11301 upheld the Pharmacy Board of Victoria’s findings of discreditable conduct. In the Mercer case the pharmacist was absent from the pharmacy while it was open and professional services were provided. The Loewy case dealt with the supply of huge quantities of ephedrine to customers. Both Mr and Mrs Loewy were owners but as Mrs Loewy was not directly involved with the management of the pharmacy, she was reprimanded and fined whereas Mr Loewy’s registration was suspended. The case of *Adamson v the Pharmacy Board of Tasmania* [2004] TASSC 32, a case that involved a dispensing error, demonstrates the court’s approach in regard to the need for pharmacists to follow practice standards.

These cases demonstrate the consistent approach with regard to the requirement that pharmacists need to follow legislative provisions that guide the practice of pharmacy. Of specific interest is the case of *Ha v Pharmacy Board of Victoria* (2002) VAR 322, as this case did not directly involve the practice of pharmacy. Mr Ha, a pharmacist, during job interviews indecently assaulted two young females (14 and 20 years) who applied for pharmacy assistant positions. In the Supreme Court of Victoria, Gillard J acknowledged that, in issues that relate to the practice of a pharmacist [at 84]:

... the standard that one would expect of the reasonable competent pharmacist or 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 further observed that the inappropriate behaviour of the appellant ‘was not confined to the practice of pharmacy’; however, he postulated that the Pharmacy Board had a joint focus, namely the protection of the public as well as the protection of the reputation of the profession itself.

These cases consistently demonstrate the courts’ approach towards the requirements that pharmacists need to follow regulatory requirements and practice standards. It also demonstrates the important role of the pharmacy registering authorities with regard to disciplining pharmacists for breaches that do not directly relate to pharmacy practice, but which impact on the reputation of the profession.

AUSTRALIAN PROFESSIONAL NEGLIGENCE

Disciplinary proceedings through the pharmacy registering authorities to the courts are distinct from cases 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 (Forrester & Griffiths, 2005).

There are very few reported Australian cases that have been through the adversarial court system, involving pharmacists in claims of professional negligence. Kiel (2005) noted that this does not mean cases have not been initiated, but rather reflect the fact that pharmacist indemnity insurers tend to settle out of court. However, payout data is not available from Pharmaceutical Defence Limited (PDL) is a Corporate Authorised Representative of Guild Insurance and provides specialised indemnity insurance for the pharmacy profession. Details are available at PDLs website at http://www.pdl.org.au/aboutus. Viewed 13 march 2006
Defence Limited (PDL). An explanation for the unavailability of incident data by PDL may be explained by the fact that professional health insurers have traditionally been reluctant to make data available. The reason quoted for this is that incident report information is considered ‘commercially sensitive’ (Forrester & Griffiths, 2005, p. 82). The unavailability of data was highlighted by Tito in 1994 through the Australian Review of Professional Indemnity Arrangements (Tito, 1994, pp. 17, 20):

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.

As indicated by Tito, incident data should be made available, as the information should be used to develop risk management processes and as examples in the training of graduates. Tito (p. 248) 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.

PDL reports only limited data regarding incident reports filed, and the reported information does not give statistics on the seriousness of errors (Pharmaceutical Defence Limited, 2005a). Therefore, Australian data involving pharmacists’ incidents and claims is not publicly available. However, incident data provides valuable insights into the vulnerabilities of dispensing procedures and identifies areas for improvement. The data should be used to develop measures and systems to prevent medication errors and hence the lack of available information precludes the profession from identifying practice shortcomings that need to be addressed to prevent similar incidents in the future.
In terms of a civil action of negligence, a person alleging 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, and the breach thereof resulting in damage suffered by the person. 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:

1. A duty of care was owed by the pharmacist (defendant);
2. There was a breach of that duty in that the pharmacist’s conduct fell below the required standard of care, which include omitting or failing to do something or by doing something incorrectly;
3. The breach of duty caused or materially contributed to the damage suffered – be it physical, mental or economic loss; and
4. 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 *Donohogue 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 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 UK case of Bolam v Friern Barnet 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. 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 Australian High Court in Rogers v Whitaker (1992) 175 CLR 479 held that the Bolam principle had no application to the giving of 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 [at 487]:

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 chose 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 depend 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 judgement 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 the provision of 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 judgement 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 their role increasingly extends to an advisory role through the provision of information. On a daily basis pharmacists need to counsel particular patients to ensure they're 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 judgement 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, such as computer systems that maintain patient profiles and automatically warn of drug interactions, expand the capabilities and responsibilities of pharmacists, 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 not been well defined (Kiel, 2005). Therefore, pharmacists’ civil liability in Australia has not been clearly identified.

In predicting pharmacists’ potential civil liability, two issues would need to be considered, namely:

1. The changed role of pharmacists, which increasingly extends to an advisory role through the provision of information as well as other roles (e.g. diagnosing and prescribing); and
2. 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 new civil liability Acts in the various Australian states and territories would also be considered by the court, and accordingly will be discussed in detail.

**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 (Chambers & Krikorian, 2003).
The Review Panel made 61 recommendations, all impacting on claims involving personal injury or death as a result of negligence (Australia. Treasury. Law of Negligence Review Panel, 2002). The recommendations that could potentially impact upon the practice of pharmacy are those that involve: (1) the standard of care with respect to the treatment of patients; (2) the standard of care relating to information provided to patients; and (3) new evidential rules relating to expert evidence.

In regard to the standard of care applicable to the treatment of patients, the Panel recommendation supported the test laid down in the *Bolam* case (Madden, 2003; , 2004), namely that the opinion held by a significant number of respected practitioners within the field should be used in assessing the standard of care in a specific case.

The Panel recommended six guiding principles regarding the standard of care relating to information to be provided to patients (Chambers & Krikorian, 2003, p. 38):

1. Two types of duty to inform: a proactive duty and a reactive duty
2. The proactive duty to inform is an objective test and should take into consideration the personal characteristics of the patient. It requires the medical practitioner to take reasonable care to give the patient such information as a reasonable person in the patient's position would, in the circumstances, want to be given before making a decision to undergo treatment.
3. The information to be given to the patient should be determined by reference to the time at which the relevant decision was made by the patient and not a later time.
4. The proactive duty to inform is not breached if the risk or other matter would, in the circumstances, have been obvious to a reasonable person in the position of the patient, unless the giving of the information is required by statute.
5. Obvious risks include risks that are patent or matters of common knowledge and can include risks of low probability. Exceptions to the proactive duty were listed and include where the patient explicitly or impliedly informs the practitioner of not wanting to be given the information, emergency situations, therapeutic privilege and an obvious risk.
6. The reactive duty to inform applies a subjective assessment.

In regard to expert evidence, the Panel suggested that jurisdictions adopt a system of court-appointed experts on a trial basis for three years.
As a result of the Panel’s recommendations, civil liability legislation was introduced in all Australian jurisdictions (Doepel, 2003), as summarised in Table 2.2.

Table 2.2: Sources of civil liability legislation.

<table>
<thead>
<tr>
<th>Location</th>
<th>Legislation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Queensland</td>
<td>Civil Liability Act 2003 (Qld), Personal Injuries Proceedings Act 2002 (Qld)</td>
</tr>
<tr>
<td>NSW</td>
<td>Civil Liability Act 2002 (NSW), Civil Liability Amendment (Personal Responsibility) Act 2002 (NSW)</td>
</tr>
<tr>
<td>ACT</td>
<td>Civil Law (Wrongs) Act 2003 (ACT), Civil Law (Wrongs) Amendment Act 2003 (ACT)</td>
</tr>
<tr>
<td>South Australia</td>
<td>Volunteers Protection Act 2001 (SA), Recreational Services (Limitation of Liability) Act 2002 (SA), Wrongs (Liability and Damages for Personal Injury) Amendment Act 2002 (SA)</td>
</tr>
<tr>
<td>Tasmania</td>
<td>Duties Act 2001 (Tas), Civil Liability Act 2002 (Tas)</td>
</tr>
<tr>
<td>Northern Territory</td>
<td>Personal Injuries (Liabilities and Damages) Act 2003 (NT), Personal Injuries (Civil Claims) Act 2003 (NT)</td>
</tr>
</tbody>
</table>

Section 21 of the Civil Liability Act 2003 (Qld) 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:

S21 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 Civil Liability Act 2003 states in section 22:

**S22 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 sub-section (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 on an individual or the giving of contraceptive advice on 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 postcoital contraceptive.

The impact of the new legislation on health professionals, and specifically on pharmacists, has not yet been tested in the courts, and it has been suggested that the real impact of the changes effected by the civil liability Acts will not be apparent for some years (Madden, 2003).

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 their main role. While this expanding and evolving role calls pharmacists’ potential liability into question, Sweet, Tatro & Whitsett (2004) observed that it is not possible to lay down broad statements concerning the pharmacist’s legal duty that would be applicable in all cases. However, as pharmacy moves into unprecedented areas, it is useful to examine recent international trends to assist in predicting where the law is going in respect to developing a normative duty for pharmacists.

**UNITED KINGDOM (UK) PROFESSIONAL NEGLIGENCE**

The regulation of the practice of pharmacy in the UK is complicated and governed by at least 90 Acts of Parliament and 39 European Directives (Tullett et al., 2003). Allegations of professional misconduct are dealt with by the Statutory Committee of the RPSGB. A pharmacist in the UK can be charged either with criminal charges in respect of a dispensing error, or an action of negligence in the civil courts (Appelby & Wingfield, 2005).

Therefore, unlike Australia, any dispensing error can result in criminal charges in the UK. These charges can follow under section 64 of the *Medicines Act 1968* (UK) (Nathan, 2004). The offence is one of strict liability; that is merely making a dispensing error is a criminal act, even though there is no intention to do anything unlawful and even if no harm results. One such case was the 2000
case against two staff at Boots the Chemist (Pharmaceutical Journal, 2000). In this case a pharmacist and pre-registration graduate were charged with manslaughter for failing to prevent a fatal dispensing error when preparing a mixture for an infant. The mixture was compounded using concentrated instead of double-strength chloroform water. However, at court, the Crown prosecution agreed to drop the charges of manslaughter and to substitute prosecutions under section 64 of the Medicines Act 1968 for supplying a medicine 'not of the nature and quality demanded'.

Researchers from the West Midlands Centre for Adverse Drug Reactions identified that up until the end of 2005, 36 doctors and 17 pharmacists had been charged with manslaughter (Pharmaceutical Journal, 2006). Of those charged, nine doctors and two pharmacists had been convicted. The RPSGB has stated that the prosecution of pharmacists with manslaughter following a patient’s death as a result of a medication error is unlikely to improve patient safety. The Society has argued that it does not promote the finding of the root causes of mistakes (Royal Pharmaceutical Society of Great Britain, 2006a). Hence, the Society is currently seeking the decriminalisation of dispensing errors following a discussion paper that indicated a serious under-reporting of errors and near misses due to the potentially devastating results to practitioners following errors.

**UK Negligence claims:**

Although the possibility of criminal charges exists, a pharmacist is more likely to face an action for negligence in the civil courts following a dispensing error. Mullan (2000) indicated that as a general principle, it is established in UK case law that the relationship between the pharmacist and the patient is one that gives rise to a duty of care. It has been reported that the number of negligence claims against community pharmacists in the UK is on the rise, as is the overall cost of settling them (Thompson, 2003). As in Australia, few cases proceed to the courts, as insurers prefer to settle these cases quietly, rather than to risk an adverse result with unwanted media attention and significantly increased legal costs (Merrils & Fisher, 2006).
Collins v Hertfordshire County Council [1947] 1 KB 633, a case that involved the dispensing of the wrong medicine, demonstrates the UK court’s approach towards pharmacists’ responsibility to question the doctor if in doubt of the appropriateness of prescribed medication. In Prendergast v Sam & Dee Ltd (1989) 1 MLR 36, the court supported this approach, and held that a pharmacist has a responsibility to contact the prescriber if in doubt. In Dwyer v Roderick (1983) 127 SJ 805, Justice Stuart-Smith rejected the pharmacist’s argument that his position is secondary to that of the doctor, and 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:

... pharmacists 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 recent High Court case of Horton v Lloyds Pharmacy Ltd (2006) (Appelby, 2007, p. 105). The Court ruled that the conduct of the pharmacist ‘fell below the standards which could reasonably have been expected of a reasonable and competent pharmacist’.

In each of these cases the 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. Although the cases confirm that the UK courts interpret the relationship between the pharmacist and patient as one giving rise to the imposition of a duty of care, the cases focus on technical accuracy. Hence, the question has been raised by legal experts in the UK (as in Australia) whether the pharmacist is under any duty of care to give warnings about medicines that are correctly prescribed, and whether pharmacists need to discuss the prescribed therapy with the patients. Mullan (2000) is of the opinion that the UK courts will follow a similar approach to the USA, as the imposition of a duty of care in those circumstances would accord with current pharmacy practice.

New roles for pharmacists in the management of patients with chronic diseases and the prescribing of medicines are currently being implemented in the UK.
This will add to pharmacists’ potential legal liability. As in Australia, the pharmacy profession in the UK, has been seeking to move away from a mechanistic role in the medication distribution process, and pharmacists have accepted increased responsibility towards patient care. However, the legal liability in regard to these evolving roles is still unclear in the UK, as is the case in Australia.

**UNITED STATES OF AMERICA (USA) PROFESSIONAL NEGLIGENCE**

Negligence claims against health professionals in the USA are more common than negligence claims in Australia and the UK. This is mainly because in the USA there are no patient cost disincentives to initiate legal action, e.g. an absence of the ‘loser pays’ legal cost rule (Tito, 1994). Different degrees of negligence charges exist, namely ordinary negligence, per se negligence (statutory negligence), gross negligence, or criminal negligence. These charges differ in regard to the degree of carelessness divided by the probability of harm and the implied mindset of the professional causing the harm. However, most health professional negligence cases involve ordinary negligence (Harris *et al.*, 2006).

Traditionally, the USA courts imposed liability solely upon pharmacists for correctly filling prescriptions. Prior to the 1990s, the courts held that a pharmacist had no duty to warn the patient or notify the prescriber in the case of over-dosages or adverse reactions. Attempts to impose liability based on theories of strict liability, duty to warn, and breach of warranty were largely unsuccessful (Apter, 1991; Asbury, 2000; Green, 1991). The initial approach taken by the USA courts was therefore to decline to impose liability on pharmacists for anything other than mechanical dispensing errors.

The courts followed the learned intermediary doctrine, in which the prescribing physician was the ‘learned intermediary’ between the drug manufacturer and the patient. Under the doctrine, only physicians had the duty to warn patients of medication adverse effects, as only physicians could relate the characteristics of the medicine to the ‘physical idiosyncrasies of the patient’. Courts therefore
viewed it as only the prescriber’s responsibility to discuss medication issues with patients, and indicated that pharmacist interference could potentially confuse patients. This approach had been criticised by a number of legal commentaries (Asbury, 2000; Brushwood, 1991; Green, 1991).

However, recent USA case law indicates the courts’ approach towards pharmacists’ legal liability is influenced by changes in legislation and the pharmacists’ changed role in health care. Courts are now allowing new and unprecedented theories of liability claims to move forward, and over the last 20 years, pharmacists in the USA had been found liable for a range of pharmacy practice services. Pharmacy legal textbooks and law journals describe many cases that indicate that the courts are now considering the altered professional context in which pharmacists practise and are allowing novel and unprecedented theories of liability claims (Dwyer, 1997; Asbury, 2000; Sweet et al., 2004).

Court decisions have, over recent decades, verified that the pharmacist has drug expertise as well as the personal knowledge of a particular patient and is therefore subject to potential liability when an error occurs. Pharmacists have been found negligent in the dispensing of prescription items, failing to detect prescription errors, failing to warn patients and a variety of system errors (Kiel, 2005; Sweet et al., 2004).

This change in approach has resulted from the passing of the Omnibus Budget Reconciliation Act of 1990 (OBRA) by Congress (Asbury, 2000). This Act contains provisions affecting how pharmacists handle prescription processing, and defines the minimum standards of care for pharmacy practice. The goal of OBRA 90 was to improve patient medication therapy by ensuring prescription medicines are appropriate, medically necessary, and not likely to result in adverse medical effects. OBRA 90 mandates that pharmacists accept a more active role in medication therapy by inquiring into patients’ conditions, reviewing their relevant medical history, and performing medication counselling. To carry out this mandate, individual states were required to implement medication use review programs to improve the quality of pharmaceutical care.
USA Negligence claims:

In *Stebbins v Concord Wrigley Drugs, Inc.* (1987) 416 NW 2d 387-8, the court affirmed the traditional approach of a negligence claim in favour of the pharmacy on the grounds that the dispensing pharmacist had no duty to warn the plaintiff of the medicine’s potential side effects. In this case the plaintiff alleged she sustained injuries as a result of a physician’s and pharmacist’s failure to warn her of the sedative side effects of a prescribed medication. Similarly, in *Adkins v Mong* (1988) 425 Mich Ct App 151, the court concluded that other jurisdictions consistently rejected the existence of such a duty, and held that ‘there exists no legal duty on the part of a pharmacist to monitor and intervene with a customer’s reliance on drugs prescribed by a licensed treating physician’ (Sweet *et al.*, 2004 p. 403). In this case the plaintiff alleged negligence and malpractice on the part of the pharmacist for supplying the plaintiff with excessive amounts of prescription medication over a six-year period, resulting in severe drug addiction. The plaintiff claimed the pharmacist had a duty to monitor patients, and should maintain a detailed and accurate patient profile that should be used to identify addicted customers and to act on this information either by refusing to fill prescriptions or notifying the physician or warning the customer.

The court continued with the traditional approach, and in *McKee v American Home Products Corp.* (1989) 782 Wash 1045 held that a pharmacist who accurately filled a prescription issued by a licensed physician had no duty to warn the customer of the potential risks associated with the medication. In this case the plaintiff brought a negligence action against a pharmacist who correctly filled her validly written prescriptions for amphetamines for ten years. The plaintiff asserted the pharmacist had to warn her of the serious side effects, including the medicine’s abuse and addictive potential. The 1991 case of *Coyle v Richardson-Merrell, Inc.* (1991) 584 A 2d 1383 similarly rejected the pharmacist’s duty to warn, and held that to require pharmacists to warn could confuse patients. The plaintiff argued the pharmacist had a duty to warn her
about the potential birth defects associated with an anti-nausea medication used during pregnancy.

However, more recent USA court decisions have verified that the pharmacist has medication expertise as well as the personal knowledge of a particular patient, and is therefore subject to potential liability when an error occurs. USA courts now continuously hold pharmacists negligent for not warning patients about medicines. A number of cases confirm this changed approach, namely: Lasley v Shrake’s Country Club Pharmacy, Inc. (1994) 880 Ariz Ct App P 2d 1129, Morgan & Pettus v Wal-Mart Stores (2000) Tex App 5282 and the more recent case of Cottam v CVS Pharmacy (2002) 436 Mass 316, 764, NE 2d 814.

Although the major change in approach started in the early 1990s with the implementation of OBRA 90, already in 1986 in Riff v Morgan Pharmacy (1986) 508 Pa Super Ct A 2d 1247, the court reviewed pharmacists’ training, internship requirements, and comprehensive licensure examination and stated that (Sweet et al., 2004 p. 395):

… 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.

The nature and extent of a pharmacist’s duty to warn a patient about a contraindication was confirmed by the Supreme Court of Illinois in Heidi Happel v Wal-Mart Stores Inc. (2002) 766 Ill NE 2d 1118. The court found that the pharmacist had a legal duty to warn either the doctor or the patient about a contraindication. In Dooley v Everett et al. (1990) 805 Tenn App SW 2d 380 and Baker v Arbor Drugs (1997) 544 Mich App NW 2d 727, the courts held pharmacists negligent for not identifying important medication interactions.

The USA approach has therefore changed significantly over the last two decades, and the courts have found pharmacists liable for their failure to warn the patient or to notify the prescriber in the case of over-dosages or adverse reactions. This changed approach has been criticised by some, who argue that judicial recognition of pharmacists’ increased liability could displace the
physician’s role, thereby compromising patient care (Fox, 2001). It has also been stated that such liability may have fatal effects on the efficiency and efficacy of pharmacist care by encouraging pharmacists to act contrary to the public interest through a ‘don’t ask, don’t tell’ policy (Casey, 2005). This theory presumes that, if pharmacists refuse to ask customers about their medical history (don’t ask), they would not be liable for failing to warn (don’t tell), as they do not have the requisite knowledge upon which to form a clinical opinion and advise the customer (to tell).

The more recent cases demonstrate the USA courts’ approach towards the changed role of the profession. Although these cases demonstrate the current approach in the USA and not necessarily the approach that will be followed in Australia, they help to predict Australian pharmacists’ potential duty of care regarding patient care services. The cases should therefore assist the profession in developing precautionary practices.

Disciplinary and negligence cases represent those instances in which an error caused a sufficiently significant impact for it to be reported to a disciplinary body, or where civil litigation followed. Many more errors occur than are acted on, because the outcome of these errors was not considered to be of significance. Although not all errors lead to incidents, it is important that all errors be recorded, as the data has to be used to identify common situations when errors occur, as well as any trends. This information is valuable in the development of risk management strategies.
2.5 MEDICATION INCIDENTS

The extent of medication related incidents in Australia was highlighted by the Australian Council for Safety and Quality in Health Care 2002 Report entitled the Second National Report on Patient Safety – Improving Medication Safety (Safety & Quality Council). According to the report, between two and three per cent of Australian hospital admissions are related to problems with medicines, which can originate either within the community or within the hospital. It was estimated that these medication-related problems result in around 140,000 hospital admissions in Australia each year, costing about $380 million per year in the public hospital system alone. Australia is not unique and it has been estimated that for every US$1 spent on medicines, another US$1 is spent paying for problems associated with the use of the medicines (Posey, 2003). The United States of America Institute of Medicine (IOM) estimated that as many as 7,000 Americans die each year from medication errors (Kohn et al., 2000).

Yet relatively few cases progress to the courts, and accordingly risk management remedies are unclear.

THE MEDICATION MANAGEMENT PATHWAY

The medicines pathway has been identified as complex and involving many processes and individuals (Stowasser et al., 2004). To assist in developing medication management processes, the Australian Pharmaceutical Advisory Council (APAC), is a consultative forum bringing together key stakeholders to advise the Australian Minister for Health and Ageing on medicines policy issues. Details are available at the APAC website:

13 A medication related incident involves patient harm and/or a complaint. Not all errors result in harm (and therefore incidents) and not all incidents are a result of an error (e.g. an idiosyncratic adverse drug reaction) (Semple & Roughead, 2005).

14 Now the Australian Commission on Safety and Quality in Health Care which is funded by the Australian, State and Territory Governments to develop a national strategic framework and associated work program that will guide its efforts in improving safety and quality across the health care system in Australia. Details are available at the Commission’s website:


15 The Australian Pharmaceutical Advisory Council (APAC), is a consultative forum bringing together key stakeholders to advise the Australian Minister for Health and Ageing on medicines policy issues. Details are available at the APAC website
Council (APAC) developed a medicines management cycle that focuses on the key components of medication management (Figure 2.1). There is potential for error throughout the medication management system and pharmacists should play a major role throughout the pathway to ensure safe medication practices.

Research by the USA Institute of Safe Medication Practices (ISMP) indicated that unintentional overdose accounted for 40% of emergency department visits, and represented the most prevalent mechanism of injury (Hahn, 2007). The ISMP also found that common misuses leading to adverse medication events are taking incorrect doses, taking doses at the wrong times, forgetting to take doses, or stopping the medication too soon. All of these are non-adherence problems that pharmacists can potentially play a significant role in addressing. However, it is not known to what extent community pharmacists have implemented systems to address these issues.

APAC has played a major role at policy level and has developed a range of guiding principles that outline the steps involved and the processes that need to be put in place in the medication management system. These include: Guiding principles to achieve continuity in medication management (2005); Guiding principles for medication management in the community (2006); and Guidelines for medication management in residential aged care facilities (2002). These guidelines and principles are targeted at all levels of health and community care service providers and indicate the complexity of the medication management pathway.

Viewed 5 July 2007
Figure 2.1: The medication management cycle (Australian Pharmaceutical Advisory Council, 2005 p. 11).
MEDICATION INCIDENT DATA

Much work has been done in recent years to promote the recording and monitoring of medication incidents in hospitals. A hospital medication incident and/or error can potentially occur at any stage of the medication pathway from diagnosis and prescription writing by the prescriber, through to the dispensing of the medication by the pharmacist and the administration thereof by the nurse (Saferhealthcare, 2006). Various health professionals are involved in the medication chain, and hospital interventions implemented in Australia to reduce errors therefore follow a multi-professional approach. Interventions introduced over recent years include the development of alert cards, the development of education tools and guidelines for high-risk medications, an increased emphasis on a ‘no-blame’ culture and the promotion of open disclosure (Safety & Quality Council, 2003; , 2005). Prospective medication chart reviews by pharmacists has also been identified as an important risk management strategy for reducing prescribing errors (D'Souza et al., 2004).

Electronic prescribing has been introduced by some hospitals which, although not without its problems and associated errors, should reduce the 2-5% error rate with handwritten prescriptions and medication charts, as reported in the Safety and Quality Council Report (Safety & Quality Council, 2002). Hospital dispensing error rates are estimated to be considerably less common than prescribing errors, and two Australian studies conducted in the early 1990s indicated dispensing error rates fell between 0.08% and 0.8% (De Clifford, 1993; Thornton et al., 1990). However, more up-to-date Australian statistics are not available.

Despite the work done in recent times to develop medication safety processes within the hospital system, it has been pointed out that little is known about medication incidents in community pharmacies in Australia (Semple & Roughead, 2005). This opinion was supported by Newgreen, Pressley & Marty (2005), who indicated that little has been published on dispensing errors in community pharmacy.
The potential impact community pharmacists could have in medication management was highlighted by the *Patient Safety Report*. This report estimated that from the more than 100 million general practice encounters and the more than 190 million prescriptions dispensed by community pharmacies per year, approximately 400,000 are thought to involve adverse medication events (Safety & Quality Council, 2002). Similarly, research analysing the medicines most commonly involved in medication-related problems indicated that those problems occur commonly in the community setting in Australia (Roughead *et al*., 2004). Community pharmacists should therefore play an important role in identifying and solving these medication-related problems. With more professions being given limited prescribing rights, for example optometrists and nurse practitioners, this role will even become more important.

However, quality information on community medication incidents is lacking; specifically, information about community pharmacy medication interventions and errors. Australia is not unique, and a study in the USA indicated that only 21% of community pharmacists in Vermont who participated in research reported medication interventions to the United States Pharmacopeia Medication Errors Reporting (USP MER) program (Kennedy & Littenberg, 2004). Yu *et al*. (2005) identified that the poor standardisation of terms and definitions used by organisations involved in medication safety contributes to the unknown statistics of medication incidences as it leads to differences in the functional meaning and classification and analysis of incidents.

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. Thus, the lack of incident information is a matter of concern, as medication incident data are needed to develop risk management procedures.

Information about complaints filed by pharmacy registering authorities provides some insight, although this information only represents cases reported to the registering authorities. Nonetheless, the information can be used to identify trends in the number of errors being reported and the type of errors being made. A survey by Newgreen, Pressley & Marty (2005) of complaints received
by the Pharmacy Board of Victoria indicated that over the 78 month period covering 1 July 1998 to 31 December 2004, 45% (73) of the 162 complaints received by the Board were associated with dispensing errors. Labelling errors accounting for 21%, and selection errors for 74%, of the complaints. The remaining errors were either the dispensing of expired medicines, or the wrong quantity. Of specific interest is the fact that no therapeutic errors were reported. A possible explanation for this may be that therapeutic errors may not be recognised as an incident by the parties involved (patient, prescriber or pharmacist) when the outcome is not of a serious nature. Another explanation is that patients may not be aware of the changed role of pharmacists, and therefore do not realise the pharmacist had some responsibility in preventing the therapeutic error.

**DISPENSING ERRORS**

A UK study involving 35 pharmacies indicated an incidence of 22 ‘near miss’ errors and four actual dispensing errors for every 10,000 items dispensed, which calculated to a dispensing error rate of 0.04% and a near miss rate of 0.22% (Ashcroft et al., 2004). Another UK study of four primary care pharmacies indicated a 0.08% dispensing error rate and a 0.48% near miss rate (Chua et al., 2003). Both studies required self-reporting, which could have affected the outcomes, as people tend to not identify their own mistakes. A more alarming study is a USA observational study of 50 pharmacies located in six cities, which indicated a dispensing accuracy rate of 98.3%, equating to about four errors/day in a pharmacy filling 250 prescriptions daily (Flynn et al., 2003).

More than 50% of dispensing errors reported to Guild Insurance in Australia relate to human error (Guild Insurance/Guildwatch, 2006). With regard to the most common pharmacy dispensing errors, PDL identified the two most frequent causes as selection of the incorrect strength of a medicine, and selection of the incorrect product (Pharmaceutical Defence Limited Annual Report, 2004b). Similarly, the Chemists Defence Association in the UK reported that the most common cause of claims is dispensing the wrong
medicine, followed by dispensing the right medicine in the wrong strength (Thompson, 2003). These ‘slip/lapse’ errors often occur when different products have similar packaging or names that look or sound alike.

A significant reduction in dispensing errors could be achieved through the appropriate use of barcode scanners during the dispensing process, evidenced from research conducted in the USA (Poon et al., 2006). The use of barcode scanners had hence been identified by Guild Insurance as a tool for reducing dispensing errors (Guild Insurance/Guildwatch, 2006). However, it has not been published to what extent community pharmacists in Australia utilise barcode scanners appropriately in the dispensing process.

Apart from those packaging and naming issues contributing towards dispensing errors, similar OTC product issues have also been identified. Semple & Roughhead (2005) indicated that the ‘branding’ strategy of OTC products, which leads to the proliferation of products with similar names but often different ingredients and different strengths, may lead to increased risk of selection errors by pharmacy staff or consumers.

Medication incident data should be used to determine situations that commonly lead to incidents, as well as incident trends. Incident information is useful in the identification of risk areas and the subsequent development of risk management procedures. However, there is a paucity of information about community pharmacy incidents in Australia. It is also not known what pharmacists’ attitudes are towards risk management and the actual procedures implemented by them to assist with risk management.

2.6 QUALITY AND RISK MANAGEMENT

Similar to medical practice, pharmacy practice requires both quality assurance and risk management (Niselle, 2004). Quality assurance activities and risk management techniques in health care frequently overlap as they share the goal of minimising adverse patient outcomes. This overlap is reflected in the
introduction of the role of the Quality/Risk Manager, a hybrid position in many health care organisations to ensure congruent outcomes from these two important functions. This section will focus on the risk management process as well as a framework for quality assurance in health care.

THE RISK MANAGEMENT PROCESS

The term risk management has many definitions. However, a common attribute of risk management is a focus on maximising positive outcomes and limiting unwanted effects (Benrimoj, 2005). It is not only about treating or responding to the negative consequences of systems or process failure. Risk management also includes the analysis of the potential for risk and the design of systems and processes to proactively address and alleviate a variety of possible negative outcomes.

The Australian/New Zealand Standard: Risk management provides a generic framework for establishing the context, identifying, analysing, evaluating, treating, monitoring and communicating risk (Standards Association of Australia, 2004b). This Standard was used to evaluate the extent to which the Standards for the Provision of Pharmacist Only and Pharmacy Medicines in Community Pharmacy (S2/S3 Standards) followed a risk management approach (Benrimoj, 2005). The S2/S3 Standards were subsequently updated during 2005 to address identified shortcomings and the new S2/S3 Standards were released in early 2006. However, no similar evaluation of the Professional Practice Standards has been conducted to date, and this needs to be addressed by the professional organisations

The objective of the Australian/New Zealand Risk Management Standard is to provide guidance to organisations in the development of risk management processes to achieve the following outcomes (Standards Association of Australia, 2004b, p. 1):

- A more confident and rigorous basis for decision-making and planning;
- Better identification of opportunities and threats;
- Gaining value from uncertainty and variability;
• Proactive rather than reactive management;
• More effective allocation and use of resources;
• Improved incident management and reduction in loss and the cost of risk, including commercial insurance premiums;
• Improved stakeholder confidence and trust;
• Improved compliance with relevant legislation; and
• Better corporate governance.

Risk management is defined as 'the culture, processes and structures that are directed towards realising potential opportunities whilst managing adverse effects' (Standards Association of Australia, 2004b, p. 4). Figure 2.2 is a schematic overview of the risk management process as described in the Standard, with the key elements that should exist in an effective risk management process. Following is a short summary of the various elements:

Communicate and consult:

The system should ensure communication and consultation occurs throughout the risk management process. This requires dialogue with stakeholders where efforts are focused on consultation rather than a one-way flow of information from the decision maker.

Establish the context:

An understanding of both external and internal environments is necessary for defining the basic parameters within which risk must be managed. It also sets the scope for the rest of the risk management process, and enables the organisation to clarify its risk management objectives.

Identify risks:

This step involves a well-structured, systematic process for identifying risks and components that might make up a relevant risk. Questions that need to be asked include (Standards Association of Australia, 2004b, p. 16):

• What can happen, when and where?
• Why and how it can happen?
Figure 2.2: The risk management process from the Australian/New Zealand Standard (Standards Association of Australia, 2004b, p. 9).

**Analyse risks:**

This involves understanding the risk and combining the consequences with their likelihood. It also involves identifying the existing processes, devices or practices that serve to minimise negative risks or to enhance positive risks and assessing their strengths and weaknesses. Benrimoj (2005) indicated that qualitative analysis is most appropriate in the case of community pharmacy, followed by factual information and data (where available).

**Evaluate risks:**

The aim of this step is to make decisions based on the outcomes of the risk analysis, about those risks that need addressing and to prioritise any action. Risks should be evaluated to allow risk categories, as opposed to merely defining risk as either ‘acceptable’ or ‘unacceptable’ (Benrimoj, 2005, p. 143).
Evaluation should involve categorising risks as intolerable risk, low risk and negligible risk (Standards Association of Australia, 2004a).

_Treat risks:_

The range of options for treating the risks need to be identified and assessed, and treatment plans prepared and implemented. A number of options may be considered and applied individually or in combination. The assessment of options should balance the costs associated with implementing an option against the benefits derived from it. However, legal and social responsibility requirements should override simple financial cost-benefit analysis. Treatment plans should include (Standards Association of Australia, 2004b, p. 22):

- Proposed actions;
- Resource requirements;
- Responsibilities;
- Timing;
- Performance measures; and
- Reporting and monitoring requirements.

_Monitor and review:_

The risk management cycle should be repeated regularly to ensure the management plan remains relevant. Monitoring and review are an integral part of the risk management process. Monitoring requires routine surveillance of actual performance and comparison with expected performance (Standards Association of Australia, 2004a). Review involves periodic investigation of the current situation.

_Record the risk management process:_

Each stage of the risk management process should be recorded, including information such as assumptions, methods, data sources, analyses, results and reasons for decisions.

The Australian/New Zealand Risk Management Standard was considered an appropriate tool for use in the evaluation of community pharmacists’ risk
management processes. The Standard will therefore be used to build the framework of the data to be collected and the analysis and discussion thereof.

QUALITY ASSURANCE IN HEALTH CARE

A framework that is still widely used as an approach to the assessment and evaluation of quality assurance in health care is one designed by Donabedian (1969). Donabedian’s structure-process-outcome theory postulates a framework for the evaluation of quality of performance and delivery of health care services (Donabedian, 1969; , 1966). Although outcomes remain the ultimate validators of the effectiveness and quality of medical care, Donabedian indicated a number of considerations that limit the use of outcomes as measures of the quality of care. The first of these is whether the outcome of care is, in fact, the relevant measure, as a particular outcome may be irrelevant. To overcome this problem, Donabedian proposed an alternative approach: to examine the process itself and the settings or structure in which the care takes place. The assessment of quality can therefore be undertaken through the evaluation of the three aspects identified as indicators of quality, these being: (1) the appraisal of structure; (2) the assessment of process; and (3) the assessment of outcome (Donabedian, 1969, p. 2).

The structure is defined as the physical or organisational properties; the process is defined as what is done; and the outcome as what is accomplished (Donabedian, 1992, p. 357). Although structure, process, and outcome are not attributes of quality, Donabedian argued that they provide information from which inferences about the quality of care can be made. However, structure, process and outcome can be used to assess quality only when and to the extent that they are causally related: structure leads to process, and process leads to outcomes. … A leads to B, B to C, and so on (Donabedian, 1992, p. 357). There is not always a clear distinction between the three categories, specifically in research that is not clinical, as reported in this thesis. However, Donabedian indicated that this should not be of concern as long as we understand how A leads to B, B to C, and so on (Donabedian, 1992, p. 358).
Donabedian (1992, p. 356) also identified two closely-related activities relevant to the assessment of quality. These are referred to as: *technology assessment*, which relates to those activities meant to determine the right things to do (or the right ways to behave); and *quality or performance assessment*, which pertains to activities meant to determine whether the things known (or presumed) to be right things to do (or the right ways to behave) have in fact occurred (Donabedian, 1992, p. 356). Both of these activities are relevant to the evaluation of risk strategies in place and being followed in community pharmacy practice, and hence were included in the research.

This study is concerned with the discipline of pharmacists, as opposed to the appraisal of medical care, the context in which Donabedian’s framework was developed. The paradigm links the elements of structure and processes ‘in a model for quality assessment and systems monitoring’ (Handler *et al.*, 2001 p. 1236). Although patient outcomes did not form part of the research, it was considered that the first two elements (structure and process) provided an ideal vehicle for research directed at exploring community pharmacy risk management.

Figure 2.3 represents a diagram of Donabedian’s framework adapted to evaluate risk management within community pharmacy practice: The regulatory framework, consisting of the legislation and delegated legislation that impact upon community pharmacy practice, form the structure of the framework. The process element consists of the procedures and protocols used by pharmacists and the disciplinary action followed in cases of unsatisfactory conduct.
Figure 2.3: Donabedian’s framework for health care service quality assurance and monitoring adapted for risk management within community pharmacy practice.
2.7 RESEARCH QUESTIONS

The practice of pharmacy has changed over recent years, with greater emphasis being placed on the patient and the provision of patient care services. This expanded role of pharmacists as medication managers has resulted in changes to their professional responsibility and potential legal liability. Legal liability is related to the level of risk involved in the provision of pharmacy services. However, it is not known whether pharmacists have the necessary structures and processes in place to reduce their risk, especially in regard to the provision of newer, more comprehensive patient care services.

The combination of the Australian/New Zealand Standards on Risk Management and Donabedian’s approach form a conceptual framework for addressing the following research questions, being formulated to address specific issues relating to risk management:

1. To what extent does the Pharmacists Board of Queensland utilise endorsed standards as admissible evidence in disciplinary cases? Information on disciplinary cases should assist pharmacists in the development of risk management strategies. However, compared to certain of the interstate pharmacy registering authorities (Pharmacy Board of Victoria, 2007) and overseas publications (Sweet et al., 2004), limited information is provided to Board registrants about instances leading to disciplinary action, the disciplinary processes and outcomes, and the extent to which practice standards are used to determine the required level of practice.

2. What is the level of community pharmacists’ knowledge of the endorsed practice standards and guidelines, and to what extent do they utilise the standards to develop risk management procedures? To ensure quality, the standards should be incorporated into everyday practice. However, there is a dearth of information about the nature of community pharmacy practices (Berbatis et al., 2003) and the ways in which pharmacists are
identifying and managing risk within the standards that were developed to guide them.

3. What is the potential impact of the differential regulatory requirements between jurisdictions on the practice of pharmacy? Pharmacy registering authorities, through their role of protecting the public, impose the requirements that community pharmacists must comply with in order to provide good practice, and hence safe medication care. As these requirements vary between states and territories, this influences the way community pharmacy is practised within the various jurisdictions.
CHAPTER 3 – RESEARCH METHODOLOGY

3.1 INTRODUCTION

This chapter addresses the overall research methodology as situated within the interpretive paradigm. This is followed by an in-depth discussion of the methods chosen for collection and analysis of the data to address the research questions.

The strategies followed throughout the data collection and analysis phases were framed within the Risk Management Process and Donabedian’s Structure. Questions were specifically framed with the intention of identifying and evaluating risks by focusing on the community pharmacy regulatory structure, and the application of regulatory requirements and endorsed practice standards by pharmacists within community practice and the Pharmacists Board of Queensland.

3.2 THE RESEARCH PARADIGM

A paradigm represents a ‘world view’ or philosophical basis for investigating a researchable problem. In this case, the aim of the research was to explain a particular phenomenon by addressing ‘what?’, ‘why?’ and ‘how?’, rather than ‘how many?’ or ‘how frequently?’. Therefore, a qualitative, interpretive approach was considered most appropriate for guiding the study, as it is essentially exploratory and concerned with investigating the reality of practice in the context within which it occurs. Qualitative researchers aim to study things in their natural setting, attempting to make sense of, or interpreting phenomena in terms of the meanings people bring to them. They therefore use a naturalistic, holistic perspective that preserves the complexities of human behaviour (Greenhalgh & Taylor, 1997). As indicated by Holiday (2002), qualitative research does not pretend to solve the problems of quantitative research, but does not see them as constraints. Both qualitative and quantitative data can be
analysed to provide insight into a particular phenomenon or situation. The interpretive or qualitative data does not seek to reduce the effect of uncontrollable social variables as would be the case in purely quantitative research. Instead, it investigates these variables and issues directly from specific observations, interpreting situational distinctiveness.

3.3 RESEARCH METHODS

To ensure the method serves the intention of the research, the data collection strategy should be determined by the question(s) of the study and by determining which source(s) of data will yield the best information with which to answer the question (Merriam, 2002). This approach was followed, and a variety of strategies for gathering the required data were identified. Three methods were subsequently employed to address the research questions, namely:

1. An analysis of pharmacy disciplinary and Health Practitioners Tribunal cases and reported pharmacy incidents;
2. An analysis of in-depth interviews with community pharmacists; and
3. A comparison of the similarities and differences in the regulatory requirements of the various pharmacy registering authorities.

Mixing various methods allows for richer data gathering from a range of sources. Triangulation of the data involves seeking more than a single perspective. This process, which enables cross-data validity checks and thus strengthens a study (Patton, 2002), has become accepted as an important research strategy, as:

... no single method ever adequately solves the problem of rival causal factors. Because each method reveals different aspects of empirical reality, multiple methods of observations must be employed. This is termed triangulation. I now offer as a final methodological rule the principle that multiple methods should be used in every investigation. (Denzin 1978b:28, cited in Patton, 2002, p. 247)
This study intermixed document analysis, interviewing and a comparison of regulatory requirements. Data analysis was simultaneous with data collection which, as described by Merriam (2002, p. 14), enabled the ‘testing’ of emerging concepts, themes and categories against subsequent data, and also allowed for adjustments to be made along the way:

- The analysis of the disciplinary cases assisted the researcher in the drafting of the interview questions as the cases highlighted certain services that, if not followed, could lead to disciplinary action. The cases also indicated which practice standards were referred to and used as evidence in disciplinary cases.
- Each interview was transcribed before the following interview was conducted. This enabled the researcher to read through the transcripts and clarify issues with the participant before the next interview. This also enabled the researcher to work on interview techniques and identify those questions that were often combined, as certain statements made by participants could be connected to more than one question. The actual analysis of the interviews occurred throughout the interview period.
- The comparison of the regulatory requirements followed the analysis of the disciplinary cases and the interviews. This enabled the researcher to identify specific regulatory issues that impact on community pharmacy practice and hence assisted in the development of the questionnaire.

**METHOD 1: ANALYSIS OF DISCIPLINARY CASES AND REPORTED INCIDENTS**

Two potential consequences of pharmacy errors in Queensland involve investigations by the Pharmacists Board of Queensland and the notification of Pharmaceutical Defence Limited (PDL) by the pharmacist.

The impact of a pharmacist’s unsatisfactory professional conduct can have devastating consequences. The disciplinary process followed by the Pharmacists Board of Queensland is therefore crucial in maintaining public trust
in the profession, as is the case with the pharmacy registering authorities within the other jurisdictions.

Knowledge of pharmacy incidents reported to indemnity insurers is important in identifying error trends and areas that require increased risk management. Incident data from PDL (Qld branch) identify the number of incidents reported and the types of errors reported.

**Data gathering:**

Under section 137 of the *Health Practitioners (Professional Standards) Act 1999* (Qld), disciplinary case hearings are not open to the public. Disciplinary case documentation is available to the general public in de-identified form. Written permission for access to case files was hence sought from the Pharmacists Board of Queensland (Appendix 2). The application was successful in terms of the *Freedom of Information Act 1992* (Qld), and a contract between the Board and the researcher was subsequently signed (Appendix 3). All disciplinary case documentation was de-identified by the Board. Although Health Practitioner Tribunal hearings are in public (Section 222) and the outcomes form part of common law, the outcomes were not available online at the time of data collection. Accordingly, Tribunal cases were also requested and obtained from the Board.

Thirty six disciplinary cases were subsequently analysed to provide insight into the incidents that led to disciplinary action, the processes and evidence used to assess conduct, and the penalties imposed on pharmacists found to have transgressed professional standards. All cases were subject to disciplinary proceedings between January 2000 and October 2006, and each case satisfied the Board’s criteria of qualifying to undergo an inquiry. Cases pursued on health grounds that underwent health assessments and monitoring under Section 107 of the Act were excluded from the analysis.

Information was also obtained from PDL (Qld branch) regarding incidents reported by pharmacists for the period January to December 2006. This data
were not publicly available, and were only obtained following significant efforts and various attempts to source information from PDL. The researcher was eventually invited to attend a PDL (Qld branch) meeting and then provided with the data to be used specifically for the purposes of the research.

**Data analysis:**

The analysis of the disciplinary cases focused on the processes involved, the evidence used, and the type of incidents leading to disciplinary actions. The use of documents as a data source has unique strengths as they already exist in the situation and do not intrude upon or alter the setting in ways that the presence of the investigator might (Merriam, 2002, p. 13). The cases were summarised under the following headings:

- Date
- Type of complaint
- Category
- Evidence used
- Finding
- Action recommended

Refer to Appendix 4 for a summary of the cases under these headings. The cases relating directly to a pharmacist’s competence to practise or manage were then selected for an in-depth, thematic analysis.

**METHOD 2: ANALYSIS OF COMMUNITY PHARMACISTS’ PRACTICE**

The well-known article by James Reason (2000), *Human error: models and management*, identified two approaches towards human error problems: the ‘person’ approach and the ‘systems’ approach. The ‘person’ approach focuses on the errors of individuals, blaming them for forgetfulness, inattention, or moral weakness; whereas the ‘system’ approach concentrates on the conditions
under which individuals work, and aims to build defences to avert errors or mitigate their effects.

In health care delivery it is now acknowledged that both potential person and system errors need to be considered in the development of practice processes and procedures. Therefore, pharmacy risk management strategies should be developed to cover all potential areas where errors can occur. Protocols should address person failures, for instance aberrant mental processes such as forgetfulness, inattention, poor motivation, carelessness, negligence and recklessness. Additionally, protocols should also focus on developing reliable systems to circumvent human error, as all humans are fallible (Reason, 2000).

Successful methods of preventing errors in pharmacy practice therefore require insight and an understanding of both human and systems causes of errors. Pharmacists need to recognise the factors playing a major role in increasing the likelihood that an individual will make an error. Both human factors (such as staff training and awareness of protocols) as well as system factors (such as processes and equipment) are therefore important in the risk management process.

Data gathering:

An understanding of community pharmacy practice processes and protocols and the extent of pharmacists’ knowledge of practice standards and guidelines would assist in determining both system and person approaches implemented in practice. Obtaining information through interviews with community pharmacists was considered the most suitable method of gathering an understanding of their knowledge of, and responses to, the need for risk management procedures.

Interview approach:

Standardised open-ended interviews are used when it is important to minimise variation in the questions posed to interviewees. According to Patton (2002),
interviews should consist of a set of carefully worded questions arranged with
the intention of taking each respondent through the same sequence and asking
each respondent the same questions with essentially the same words. This
reduces the possibility of bias due to having different interviews for different
people. However, an open-ended interview approach has certain shortcomings;
for example, it does not allow the interviewer to pursue topics or issues that
were not anticipated when the interview was written. Patton thus recommended
using a combination of standardised open-ended questions with an interview
guide to overcome the shortcomings of standardised open-ended interviews.

This combined approach of using a semi-structured interview questionnaire
while allowing flexibility to explore as judged appropriate during the interview,
was regarded as most suitable for gaining the required data. It allowed more
flexibility in probing and more decision-making flexibility in determining when it
was appropriate to explore certain topics in greater depth, or even to undertake
whole new areas of inquiry not originally included in the interview instrument.

**Development of the interview tool:**

A semi-structured questionnaire was developed (Appendix 5). The questions
focused on the objectives of the research, with additional consideration of the
literature, available data from previous studies, and other factual information
such as practice standards and guidelines. Careful consideration was given to
the wording of each question, and any clarifications or elaborations to be used
were written into the interview to prompt further information. The questions
were discussed with the researcher’s supervisors for input, and minor changes
were made. The researcher also met with a practitioner-lecturer at the
University to obtain input regarding the content validity of the questions and the
overall approach. This practitioner-lecturer had more than 20 years experience
in community pharmacy practice as both a manager and owner and was an
elected Pharmacy Guild representative on the Gold Coast, and hence up-to-
date with contemporary pharmacy practice issues and challenges. Feedback
from the practitioner-lecturer indicated that the topics addressed were relevant
and the questions appropriate. A few minor changes were made.
The questionnaire was subsequently formally trialled through interviewing a community pharmacist. This pharmacist was considered an appropriate candidate for the trial as the pharmacy owned by this pharmacist provided a range of extended practice services, which included a baby clinic one day per week, medication management review services and specialist extemporaneous compounding. This pharmacist had previously been involved as a practitioner-lecturer at the University, was actively involved in the development of extemporaneous compounding practice standards, was known to promote the implementation of good practice standards and the pharmacist’s pharmacy had in recent years been the Queensland finalist in the national Pharmacy Guild Pharmacy-Of-The-Year competition. This pharmacist was hence regarded as being a leader in the profession. The trial provided valuable comment on the flow of the questions and the wording and indicated that both the content of the questions and the overall approach were appropriate.

**Sampling:**

The objective of the semi-structured interviews was to gain an understanding of the actual processes and procedures followed in community pharmacy practice, as well as pharmacists’ knowledge of the need for proper risk management. Within the qualitative paradigm, random sampling makes little sense, as it is important to select information-rich cases. Ideally, respondents are selected from those from whom the researcher can learn a great deal about issues of central importance to the purpose of the research (Merriam, 2002). This enables the selection of participants representing a wide range of practitioners.

The semi-structured interview tool development therefore encompassed the aim of the project, literature findings, available data from previous studies, peer opinion and factual information such as practice standards and guidelines. The content validity of the questionnaire tool was tested through an extensive process that involved input from a practitioner-lecturer and trialling it on a community pharmacist.
Recruitment strategy:

To assist with the selection process, an expression of interest form and information sheet were mailed to all Gold Coast pharmacies on the School of Pharmacy database (n = 95) and addressed to pharmacy managers (Appendix 6). This database was considered the best record of Gold Coast pharmacies as it contained a list of all the pharmacies and had been developed by the School over several years for pharmacy student placement purposes and kept up-to-date by the School’s Placements Officer.

Through a fax-back form pharmacists were requested to indicate their willingness to participate in an interview. Thirteen expressions of interest forms were received, representing a broad range of pharmacist demographics. A further five pharmacists were approached by the researcher to be interviewed to ensure the range of participants covered pharmacists with a broad cross-section of career paths and years of experience within the profession. This process also ensured the inclusion of a pharmacy from a semi-rural area. A pharmacy manager from a warehouse-type pharmacy was also contacted as the researcher considered it necessary to include this category of pharmacy. Hence, the process followed was a combination of participant self-selection and targeting a pharmacist to ensure inclusion of a specific category of pharmacy as well as pharmacies from both affluent and deprived areas.

All 19 of the selected participants were contacted by telephone to confirm their availability and to organise a suitable time and venue for the interviews. Respondents also received an information pack with more detailed information about the research. This pack included information about consent to do the interview (Appendix 7).

Seventeen interviews were conducted during August and September 2006. Although there were two more potential participants, the one relocated overseas and the other one continually deferred the interview. These two were not from the semi-rural or warehouse pharmacies and as no more new themes were identified during the last few interviews, saturation was achieved and the
researcher did not conduct any additional interviews. Table 3.1 provides a summary of the 17 participants’ demographic characteristics.

Table 3.1: Summary of participants’ demographic characteristics.

<table>
<thead>
<tr>
<th></th>
<th>No.</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>8</td>
<td>47%</td>
</tr>
<tr>
<td>Female</td>
<td>9</td>
<td>53%</td>
</tr>
<tr>
<td><strong>Position</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Owner-manager</td>
<td>12</td>
<td>70.6</td>
</tr>
<tr>
<td>Manager</td>
<td>5</td>
<td>29.4</td>
</tr>
<tr>
<td><strong>Pharmacy type</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Banner group&lt;sup&gt;(a)&lt;/sup&gt;</td>
<td>6</td>
<td>35.3</td>
</tr>
<tr>
<td>Independent</td>
<td>11</td>
<td>64.7</td>
</tr>
<tr>
<td><strong>Pharmacy location</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Business street</td>
<td>6</td>
<td>35.3</td>
</tr>
<tr>
<td>Next to medical centre</td>
<td>5</td>
<td>29.4</td>
</tr>
<tr>
<td>Shopping centre</td>
<td>5</td>
<td>29.4</td>
</tr>
<tr>
<td>Private hospital&lt;sup&gt;(b)&lt;/sup&gt;</td>
<td>1</td>
<td>5.9</td>
</tr>
</tbody>
</table>

<sup>(a)</sup> Banner group pharmacies are independently owned but share a common brand.

<sup>(b)</sup> This pharmacy served the hospital and community

**Conducting the interviews:**

The researcher started each interview with the following phrase:

Thank you for taking the time to see me today.

I have a series of questions to help guide the interview. There are no wrong answers to these questions, so please feel free to share your point of view and experience. The interview will be tape-recorded to help me remember all of your comments. At this point can I just check if you are happy for the interview to be tape-recorded? (Turn on recorder and say something like “is the tape-recorder close enough?”)
I would like to remind you that everything that is said will remain confidential. Your name will not appear in any reports or publications resulting from this work.

The interviews therefore took place in a confidential environment during which the participants shared their practice processes and procedures with the researcher with the understanding that the transcripts would remain confidential. The full transcripts or lengthy extracts of the interviews are therefore not included in the thesis. Interviews ranged between 28 to 66 minutes (average, 41 minutes) in duration and were tape-recorded. Field notes made during the interviews included subjective observations made by the researcher, for example the overall neatness and organisation of the pharmacy as well as the pharmacist’s motivation towards practice improvements. Participants also provided examples of various forms used eg. consent forms for the hiring of medical equipment. The field notes and examples supplemented the interviews and added to the researcher's knowledge of a specific pharmacy and understanding of practice processes and procedures.

As a clinician-educator, the researcher was respected and closely involved with the local pharmacy community, and this engendered trust, open disclosure and genuine communication. The researcher also had an understanding of local practice issues which assisted with understanding the practice context. The conducting of the interviews by the researcher herself enabled the probing of questions and giving participants the opportunity to expand on specific issues, aligned with the research topic. The researcher did consider the fact that participants could have felt uncomfortable sharing their practice information while realising the possibility of attending pharmacy meetings or continuous professional development sessions in the future with the researcher. However, the researcher carefully considered these issues and concluded that the benefits of personally doing the interviews significantly outweighed the potential limitations.

The interviews were transcribed verbatim to assist with the analysis. Analysis of interview data was enhanced by the researcher’s engagement with the field. The interviews were scanned and categorised in a reiterative process to garner
logical groupings around common concepts. Once these concepts became repetitive in revealing common meanings, saturation was considered to have occurred.

**Data analysis:**

Some analytical techniques were borrowed from the grounded theory approach. The goal of grounded theory is to derive inductively from data a theory that is ‘grounded’ in the data and emphasises discovery with description and verification as secondary concerns (Merriam, 2002, p. 7). Although the intention of this study was not to generate theory, inductive analysis and constant comparison of categories and concepts assisted in clarifying the common and distinct themes emerging from the interviews. This is one of the conventions of interpretive research. As indicated by Patton (2002, p. 125), it ‘depends on methods that take the researcher into and close to the real world so that the results and findings are grounded in the empirical world’.

Transcribed interviews were collated question-by-question and entered into the qualitative data analysis program NVivo 7 (http://www.qsrinternational.com/default.aspx). This software program helped to manage the unstructured information through the use of tools that assisted with the sorting and arranging of information. The program provided a sophisticated workspace that enabled the researcher to work through the information and identify themes.

Three main categories were identified to analyse themes, namely: issues that focussed on the (1) services provided by the pharmacists; (2) management of the pharmacy; and (3) people employed at a pharmacy. Table 3.2 is a summary of the themes that emerged.
Table 3.2: Themes identified through interview analysis

<table>
<thead>
<tr>
<th>Category</th>
<th>Themes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy services</td>
<td>• Functions which often require personal discretion and judgement</td>
</tr>
<tr>
<td></td>
<td>• Factors that impact on the provision of patient care services</td>
</tr>
<tr>
<td>Pharmacy management</td>
<td>• Issues that related to the pharmacy’s layout and design</td>
</tr>
<tr>
<td></td>
<td>• Pharmacy recordkeeping</td>
</tr>
<tr>
<td></td>
<td>• Pharmacy protocols</td>
</tr>
<tr>
<td></td>
<td>• Overall approach, knowledge and attitude towards risk management</td>
</tr>
<tr>
<td></td>
<td>• Financial issues</td>
</tr>
<tr>
<td>People employed at the pharmacy</td>
<td>• The influence of pre-registration students and young pharmacists being employed at the pharmacy</td>
</tr>
<tr>
<td></td>
<td>• Issues that relate to medical practitioners</td>
</tr>
<tr>
<td></td>
<td>• Ethical awareness</td>
</tr>
<tr>
<td></td>
<td>• Delegation of functions and workflow</td>
</tr>
<tr>
<td></td>
<td>• Utilisation of support staff</td>
</tr>
</tbody>
</table>

The quotes that related to each theme were joined using NVivo 7. This provided a full text of all the quotes relevant to each theme. The researcher subsequently continued analysing the transcripts with all the questions as well as the transcripts with the themes which enabled further content analysis and standardisation (Patton, 2002). Through this process common practice issues emerged that were correlated to practice standards and processes, patient outcomes and staffing. This analysis provided an understanding of everyday pharmacy practice – ‘the real world’ – and the information was subsequently used to formulate practice theory and risk management findings.

Each of the participants received a copy of the interview analysis and was given an opportunity to provide comment and provide feedback to the researcher.
regarding the inclusion of the selected quotes. The participants therefore gave permission for the inclusion of the selected quotes in the thesis.

**METHOD 3: COMPARISON OF REGULATORY REQUIREMENTS**

Regulation of the pharmacy profession is the principal means of ensuring public trust and confidence in the services provided by pharmacists. The regulation of health professionals in Australia has traditionally been at state level, and the states administer an extensive system of registration requirements for health professionals, including pharmacists (Palmer & Short, 2003). State and territory legislation therefore provides for the regulation of the profession throughout Australia via the pharmacy registering authorities.

Pharmacy registering authorities maintain a register of pharmacists, with those on the register entitled to practise as pharmacists; oversee the training of pre-registration pharmacists; and ensure that professional standards are maintained and that those pharmacists who failed these standards are disciplined. Not all of the authorities maintain registers of pharmacy premises, and those authorities are therefore limited in the level of control they have over pharmacy premises and ability to address deficiencies. The administrative costs of the authorities are financed through registration fees.

Although similarities exist between the legislative provisions and the powers of the individual authorities, several of the regulatory requirements vary. These differences impact directly upon the way pharmacy is practised within the various jurisdictions, and on the risk management procedures pharmacists need to implement and follow.

*Data gathering:*

A comparison of the regulatory requirements relating to the regulation of pharmacy practice and pharmacists’ registration requirements of the various pharmacy registering authorities would identify consistencies and differences
impacting upon community pharmacy practice. The eight authorities involved were the:

- Pharmacists Board of Queensland
- Pharmacy Board of New South Wales
- Australian Capital Territory Pharmacy Board
- Pharmacy Board of Victoria
- Pharmacy Board of South Australia
- Pharmaceutical Council of Western Australia
- Pharmacy Board of Tasmania
- Pharmacy Board of the Northern Territory

**Development of the data tool:**

A four-page questionnaire (Appendix 8) was designed to address the legislative requirements under the following headings:

- Professional misconduct
- Processes and procedures
- Registers
- Pharmacy premises and equipment

**Recruitment strategy:**

The Council of Pharmacy Registering Authorities (COPRA) (now the Australian Pharmacy Council) was approached for input on the questions and to discuss COPRA’s involvement in the distribution process. COPRA agreed to send out the questionnaire on behalf of the researcher. The questionnaire was subsequently sent it to all eight pharmacy registering authorities in Australian states and territories during September 2006 via an e-mail from COPRA (Appendix 9). The researcher subsequently contacted all the authorities to introduce herself, and clarify any issues. The researcher periodically contacted all authorities until all completed questionnaires had been returned by the end of 2006.
Further data were obtained through searching the authorities’ websites. Follow-up interviews were also conducted with representatives of the authorities to clarify certain issues, which helped to triangulate the data, and contributed to the confirmability of the findings.

**Data analysis:**

Appendix 10 provides a summary of the data gathered. The information was analysed using standard thematic coding and categorisation and theory development. The regulatory requirements and processes imposed through the various authorities were evaluated and compared to identify similarities and differences.

### 3.4 ETHICAL CONSIDERATIONS

The collection of data proceeded following Griffith University Ethics Committee granting approval for the study. With regard to Method 1: Informed consent was not required for the analysis of the Pharmacists Board of Queensland disciplinary cases, as the cases were de-identified. Similarly, informed consent was not required for the analysis of the Tribunal cases as these form part of case law and are therefore available to the general public.

With regard to Method 2: The expression of interest form to Gold Coast pharmacies included information about the research, and the completion and return of the form were taken as consent for participation in an interview. Interview pharmacists received an information sheet and signed a consent form before being interviewed, which included permission to be tape-recorded. Participants were informed that they were under no obligation to participate. To ensure anonymity and confidentiality, interview data were coded to protect the identities of the interviewees.
With regard to Method 3: All eight of the pharmacy registering authorities participated voluntarily.

The coded interview information and the disciplinary cases were kept in a secured, locked file accessed only by the researcher. All personal data collected were stored in a secure file as per the Griffith University ethics requirements.

3.5 VALIDITY, RIGOUR AND CREDIBILITY OF THE FINDINGS

The credibility of qualitative inquiry inter alia depends on rigorous methods for gathering the data and the analysis thereof, with attention to issues of credibility. According to Patton (2002, p. 553), this depends on the analyst’s insights and conceptual capabilities.

As a pharmacist who has worked within a range of settings, including policy development and the management of programs to implement policy, as well as hands-on delivery of pharmaceutical services, the investigator brings to the research familiarity with pharmacy practice and the pharmacy profession. The researcher gained extensive regulatory experience in South Africa, and understands the processes and structures of judgements and decisions made in disciplinary proceedings. She has played a major role in the development and writing of pharmacy practice legislation and good pharmacy practice standards and guidelines in South Africa. She gained experience of the policy and legislative process in Australia through the evaluation of the Health (Drugs and Poisons) Regulation 1996 (Qld), and the subsequent drafting of changes to legalise the roles of hospital pharmacy support staff. She has worked both in hospital and community pharmacy practice in Australia. The researcher also lectures pharmacy law and ethics to pharmacy students, and has developed a high level of knowledge of all the legislation and common law impacting upon the practice of pharmacy.

Close engagement with the data allowed reconstruction of the realities of the data and processes under study. It also permitted an interactive link between
the investigator and what was being investigated. According to Denzin &
Lincoln (2000), this affects and influences the inquiry. To some extent, the
researcher’s values dictate the way the study is framed, the way questions are
posed, the way data are analysed, and the way findings, described as ‘value
mediated’, are argued (Denzin & Lincoln, 2000, p. 119).

The use of multiple methods aimed to reveal different aspects of risk
management in pharmacy practice, and allow for cross-data consistency checks
(Patton, 2002). Triangulation of the data gathered through the three methods
aimed not only to add to the credibility, but also to strengthen the confidence of
the conclusions. This process aimed to illuminate various aspects involved in
risk management within community pharmacy practice, and to reduce the risk of
systematic bias. Reduction of ‘data distortion’ was sought by checking the
findings against other sources (Patton, 2002, p. 563).

‘Reflexive triangulation’ is a strategy used to add the audience’s reactions to the
triangulation mix (Patton, 2002, p. 561). This strategy was used for all three
methods: The disciplinary case analysis and the outcomes were discussed with
legal officers at the Health Practitioners Board for input and verification; the
interview analysis was given to one of the participants for comment and input,
and a summary of the interview analysis was subsequently sent to all
participants for verification; and a summary of the comparison of the interstate
regulatory requirements was sent to the Australian Pharmacy Council as well as
all pharmacy registering authorities for verification and input. The objective was
to confirm the findings, seek alternative views and refine content where
appropriate.

3.6 METHODOLOGICAL LIMITATIONS

The researcher acknowledges that whilst the methodology is appropriate for the
research questions, it has certain boundaries and the following limitations are
identified:
• The methodology chosen is qualitative and this research therefore will not include statistical information about incident rates and errors;

• Due to the limited number of interview participants, conclusions may not necessarily reflect the practice of all community pharmacists in Australia;

• Although the sampling includes a warehouse pharmacy, no other big banner groups e.g. Terry White Chemists, are included. The lack of interest from big banner groups is possibly due to workload pressures;

• There are no rural pharmacies on the Gold Coast. However, a semi-rural pharmacy was included in the interviews. Rural pharmacy practices and needs may differ, for example staffing arrangements. The analysis of rural pharmacy practice could be the focus of future research.

• The community pharmacists interviewed were all willing to participate, give up time and be questioned. It is therefore reasonable to assume that they were more motivated and committed to practice developments than many other pharmacists who were not interested in being interviewed; and

• The interpretation of the data will be influenced by researcher bias.
CHAPTER 4 – RESULTS

4.1 INTRODUCTION

The study findings were derived from a triangulation of the three methods employed to gather data, namely: an analysis of the Pharmacists Board of Queensland disciplinary cases; an analysis of the in-depth interviews with community pharmacists and the comparison of the similarities and differences between the regulatory requirements of the various jurisdictions. This chapter presents the findings from all three methods in separate sections.

4.2 ANALYSIS OF DISCIPLINARY CASES AND REPORTED INCIDENTS

Analysis of the cases is presented under the following headings:

- Legislative framework
- Case categories with detailed discussions of dispensing errors; inappropriate S3 supplied; inappropriate owner supervision; and excessive pseudoephedrine supplied;
- Evidence used;
- Standard of proof;
- Sanctions imposed;
- Contribution; and
- Specific practice issues identified – namely substandard counselling; pharmacist’s practice knowledge; procedures followed after a mistake; pharmacy systems; and other contributing factors.

The case analysis is followed by a discussion of the data obtained from Pharmaceutical Defence Limited (Qld branch) regarding the incidents pharmacists reported to them between 1 January and 5 December 2006 (Pharmaceutical Defence Limited (Qld branch), 2006).
THE LEGISLATIVE FRAMEWORK

Section 8 of the *Pharmacists Registration Act 2001* (Qld) defines the objects of the Act:

a) To protect the public by ensuring health care is delivered by registrants in a professional, safe and competent way;
b) To uphold the standards of practice within the profession; and
c) To maintain public confidence in the profession.

Section 12 specifies the functions of the Board, which include ‘to promote high standards of practice of the profession by registrants’. Disciplinary proceedings are initiated and conducted by the Board under the provisions of the *Health Practitioners (Professional Standards) Act 1999* (Qld). All cases arose from initial complaints received by the Board, and were subject to disciplinary inquiries on the grounds of ‘unsatisfactory professional conduct’, which is defined in the Schedule dictionary of the Act as:

(a) professional conduct that is of a lesser standard than that which might reasonably be expected of the registrant by the public or the registrant’s professional peers;
(b) professional conduct that demonstrates incompetence, or a lack of adequate knowledge, skill, judgement or care, in the practise of the registrant’s profession;
(c) infamous conduct in a professional respect;
(d) misconduct in a professional respect;
(e) conduct discreditable to the registrant’s profession;
(f) providing a person with health services of a kind that are excessive, unnecessary or not reasonably required for the person’s wellbeing;
(g) influencing, or attempting to influence, the conduct of another registrant in a way that may compromise patient care;
(h) fraudulent or dishonest behaviour in the practice of the registrant’s profession;
(i) other improper or unethical conduct.

The Act is not only the source of the Board’s powers, but in relation to the discipline of the pharmacy profession, it also serves to provide the structural framework within which the discipline of pharmacists takes place. The Act describes the stepwise approach to be followed, which involves the referral of complaints of potentially serious nature to a Professional Conduct Review Panel
under Section 126(1)(b) of the Act. Cases involving offences of such a nature that the registrants could potentially be suspended, or his/her name removed from the register, were referred to the Health Practitioners Tribunal under Section 134(1) of the Act.

**ENDORSED STANDARDS AND GUIDELINES**

Under section 374 of the Act, the Board endorsed all practice standards and guidelines developed by the professional organisations (Pharmacists Board of Queensland, 2004). The Board also developed separate policies and guidelines, several of which overlap the endorsed standards and guidelines. Table 4.1 provides a summary of the Board’s policies and guidelines and the endorsed standards and guidelines, indicating the areas of overlap.

Table 4.1: Pharmacists Board of Queensland standards and guidelines.

<table>
<thead>
<tr>
<th>Board document</th>
<th>Endorsed Professional Practice Standards</th>
<th>Endorsed guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy and Guidelines: Distance dispensing</td>
<td>Distance supply</td>
<td></td>
</tr>
<tr>
<td>Guideline: Dose administration aids</td>
<td>Dose administration aids service</td>
<td>Dose administration aids guidelines</td>
</tr>
<tr>
<td>Guideline: Generic substitution</td>
<td></td>
<td>Guidelines for pharmacists on PBS brand substitution</td>
</tr>
<tr>
<td>Guideline: Guide to good dispensing</td>
<td>Dispensing</td>
<td></td>
</tr>
<tr>
<td>Guideline: Patient counselling</td>
<td>Counselling</td>
<td>Consumer medicine information and the pharmacist</td>
</tr>
</tbody>
</table>
EVIDENCE AND STANDARD OF PROOF

Sections 136, 179 and 219 of the Act, in dealing with the proceedings before the Board, Disciplinary Committee, Panel or Tribunal, state that:

When conducting a hearing, a board or disciplinary committee/panel/tribunal –
(a) must comply with natural justice; and
(b) must act quickly, and with as little formality and technicality, as is consistent with a fair and proper consideration of the issues before it; and
(c) **is not bound by the rules of evidence** (own emphasis) and
(d) may inform itself of anything in the way it considers appropriate.

Therefore, the rules of evidence do not strictly apply in disciplinary proceedings involving health professionals. Similar legislative provisions exist within all Australian jurisdictions in relation to the admission of evidence into disciplinary proceedings involving professionals (Forbes, 2002). 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 against the prejudicial impact that information may have on the determination. Therefore, the Board, Disciplinary Committee, Panel and even the Tribunal may admit and inform itself of matters which, 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.

The legislation entrusts the Board 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. However, although the rules of evidence do not need to be followed in disciplinary proceedings, they generally provide guidance in terms of fairness and the general conduct of proceedings (Forbes, 2002).

The common law test was 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.

As well as the opinion of the pharmacists serving on a Disciplinary Committee or Panel, additional opinion was gathered in a dispensing error case caused by the pharmacist’s misinterpretation of the prescription. This involved a small survey of nine community pharmacists working in Brisbane. Six of the pharmacists correctly identified the medicine, and while the other three interpreted it incorrectly, all stated they would have contacted the prescriber to clarify the dose. The opinion of an ‘Expert Community Pharmacist’ was also considered in one case.

Specific evidence used in the analysed cases included:

1. Legislation: A large percentage of the cases included breaches of specific sections of the *Health (Drugs and Poisons) Regulation 1996* (Qld). Other legislation referred to included the *Therapeutic Goods Act 1989* (Cwlth) and the *Drugs Misuse Act 1986* (Qld).
2. Affidavits with complainants’ recollection of what occurred and pharmacists’ written explanation of the situation were included in the investigations.
3. Pharmacy employees’ interviews in specific cases.
4. Incorrectly dispensed products or products with incorrect labels kept by the complainants.
5. Pharmacy records e.g. Schedule 8 record books and pharmacy computer databases.
6. Queensland Health inspection reports.
7. Documentation requested from outside organisations, which included: (a) information from pharmaceutical wholesalers to indicate that a pharmacy’s pseudoephedrine purchases were in excess of the national average; (b) patients’ hospital notes or information from the medical practitioner to indicate the severity of symptoms following a dispensing error; and (c) information from the Health Insurance Commission regarding pharmaceutical benefit claims.
8. Peer professional opinion.
9. The PSA Code of Professional Conduct was quoted in a few cases; however, not in a consistent way.
10. The Board endorsed S2/S3 Standards were referred to in some of the pseudoephedrine cases, however, this was not done in a consistent way.
11. The endorsed Professional Practice Standards were utilised inconsistently, and only in general; for example, no reference to the specific criteria outlined in the Standards.
12. Guidelines referred to included the PSA Guidelines for Pharmacists Providing a Methadone Service.
13. Sections from the *Queensland Methadone Program Policy, Procedures and Treatment Manual* that were directly relevant to the case were quoted in the Investigation Report to indicate the supply did not comply with the required procedures. In this case the pharmacist dispensed directly in conflict with sub-section 6.2.7, which states that:

    When take-away doses are authorized they are to be dispensed in separate bottles with the methadone dose diluted with orange juice or similar beverage (50 – 100 mL). Each take away dose is to be supplied with a child-resistant closure. All take-away doses should be labelled appropriately, including a warning of the possible associated hazards when driving or operating machinery. However, prescribers will notify pharmacists of clients who are not aware of their methadone dose (see Section 4.19, Disclosed Dose Policy), and the dose shall be omitted from the label for these clients.

14. Board policy on generic substitution.
15. Board bulletins were referred to in the pseudoephedrine cases, also by the Tribunal Judge, who specifically quoted three board bulletins issued to registrants before 1999, highlighting the conversion concerns. The bulletin with the ‘Criteria for counselling’ was referred to in two cases that involved dispensing errors, but not in other similar cases.

No consistent pattern was evident in the utilisation of endorsed practice standards and guidelines. This inconsistency is of concern, as pharmacists need to have an understanding of the main criteria that will be used in disciplinary cases. However, evidence did appear to comply with the requirement of being ‘logically probative’ (Forbes, 2002, p. 176). Evidence
supporting the registrant and indicating that appropriate procedures were followed was also admitted and considered:

The reason for the Decision of the Pharmacists Board that a ground for disciplinary action is not established is that although the registrant did mistakenly dose the patient with 625 mg instead of 125 mg of methadone as a syrup, his actions subsequent to the event complied with the accepted procedures to follow in the case of a dispensing error. In addition he went to considerable lengths to find the patient and resolve any problems resulting from the overdose despite receiving incorrect information from the patient himself.

Therefore, evidence was gathered not only to favour the complainant, but also to ensure compliance with natural justice and hence ensure a fair outcome for the registrant.

The standard of proof followed throughout the disciplinary process was 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 in regard to all disciplinary proceedings. The rationale for the lower standard is that the jurisdiction is protective towards the public, and a professional 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 (Forbes, 2002). However, according to the Briginshaw case, the clarity of proof required to discharge the burden must reflect the seriousness of the charge.

The approach applied throughout the disciplinary process is clearly demonstrated by the following:

The prescription was dispensed. Most probably the label was placed on the outer box of methotrexate tablets and given to Mr *** (along with a number of other medicines) without any counselling Ms ***.............In this matter there is no evidence that either Mr *** or Mrs *** were provided with written advice about the dose, day and time of administration for methotrexate – other than the instructions on the label placed on the outer packaging (own emphasis).

This case also emphasises two other important practice difficulties, namely:
1. The fact that the methotrexate bottle is very small, and it is therefore difficult to attach a label to it; and

2. The absence of an audit trail of the dispensing process due to dispensing software limitations. For example: software programs do not record how many labels were printed during the dispensing process, and whether a Consumer Medicine Information (CMI) sheet was printed out.

CASE CATEGORISATION

Case categories are summarised in Table 4.2. Cases with multiple breaches involving more than one category were grouped under the error category that seemed to be the most prominent in the opinion of the researcher, in consultation with Board office staff. For example: all of the dispensing errors also involved a lack of appropriate counselling but were categorised as dispensing errors as there was a direct link between the dispensing error and the incident whereas the omission of counselling indirectly contributed to the incident.

Table 4.2: Categories of analysed disciplinary cases.

<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
<th>Percentage %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dispensing errors</td>
<td>17</td>
<td>47.2</td>
</tr>
<tr>
<td>Fraud</td>
<td>7</td>
<td>19.4</td>
</tr>
<tr>
<td>Excessive pseudoephedrine supplied</td>
<td>4</td>
<td>11.1</td>
</tr>
<tr>
<td>Inappropriate owner supervision</td>
<td>3</td>
<td>8.3</td>
</tr>
<tr>
<td>Inappropriate supply of S3 product</td>
<td>2</td>
<td>5.6</td>
</tr>
<tr>
<td>Illegal export</td>
<td>2</td>
<td>5.6</td>
</tr>
<tr>
<td>Practised without registration</td>
<td>1</td>
<td>2.8</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>36</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

While all cases were evaluated, the research focus was to gather in-depth information about the four categories relating to a pharmacist’s professional competence to practise or manage, namely:
Dispensing errors
Excessive pseudoephedrine supplied
Inappropriate owner supervision
Inappropriate supply of S3 product

These four categories were considered most likely to be categorised as professional negligence in cases of civil litigation.

**CATEGORY 1: DISPENSING ERRORS**

Dispensing errors represented a significant proportion of the cases, and were indicative of the percentage of time pharmacists are occupied with the activity of dispensing and the significance of the dispensing workload. Two cases represented incidents that led directly to the death of a person.

One case involved the death of a small child as a result of a methadone overdose. The pharmacist incorrectly administered 10 take-away methadone doses to a registered addict in a single bottle rather than separate bottles. Methadone is used as a substitute in opioid dependent patients. 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. This case was referred to the Health Practitioners Tribunal.

The other case involved the death of a patient as a result of a Tramal SR® (tramadol) overdose. Tramadol is an opioid analgesic. The pharmacist dispensed the tramadol without affixing a label with proper usage instructions, and also did not provide any counselling or a CMI leaflet. Although the prescription did not include the required dosage instructions as specified in the *Health (Drugs and Poisons) Regulation 1996* (Qld), the pharmacist did not attempt to contact the prescriber to clarify the dosage. The patient took an overdose and died.
Three of the dispensing errors caused patients to be admitted to hospital. In the first case, the pharmacist dispensed Ledertrexate® (methotrexate) instead of letrozole. Methotrexate is an antifolate used in low doses (usual dose 2.5mg weekly). The usual dose of letrozole is 2.5mg daily, and due to the patient being incorrectly dispensed methotrexate, she used the methotrexate daily. After two weeks of taking the methotrexate at the dosage level appropriate to letrozole, the patient was:

...suffering from loss of appetite, extreme fatigue, very painful mouth ulcers, and cellulitis of the leg. She was urgently referred to [a metropolitan teaching hospital] by her local doctor. She was found to be pancytopenic …… She required platelet transfusion and antibiotic treatment for the cellulitis.

The second case involved dispensing the incorrect strength of a medication. MS Contin® (morphine) 100mg was supplied instead of MS Contin® 10mg. Morphine is an opioid analgesic. Subsequently, the patient took twice-daily doses of 130mg (30mg + 100mg) instead of 40mg (30mg + 10mg), and had to be admitted to hospital:

... she felt generally unwell being confused and delusional, extremely drowsy and with an incomplete memory of early hours of that day. She was seen by Dr. *** at his surgery and diagnosed with bronchitis with delusions secondary to hypoxia ……… she was still delusional and had difficulty swallowing. She was taken to [a metropolitan private hospital] where she was found to be febrile and tachycardic and was diagnosed with a chest infection. She was admitted at 1100 hrs. During the admission the dose error with the MS Contin was noticed when the medicine was handed over to be locked in the controlled drugs safe in the ward.

The third hospitalised case involved the sub-standard labelling of methotrexate tablets. In this instance the pharmacist only labelled the secondary container (the box) and not the primary container (the bottle). The patient discarded the box and subsequently used the methotrexate daily instead of weekly. The pharmacist also failed to counsel the patient regarding the side-effects, and did not provide written information:

She was admitted for treatment of her ulcerated mouth and throat, diarrhoea and high temperature..... Mrs ***'s medical notes as supplied by [a health service district] confirmed that she was admitted .... from 16 March 2004 until 19 March 2004 and again on 22 March 2004 until 27 March 2004. On 16 March she was admitted with methotrexate toxicity and received ......After being discharged on
19 March 2004 she was readmitted on 22 March 2004 as she had difficulty in swallowing due to severe mouth ulceration.

The other 11 dispensing errors resulted in less serious physical consequences for the patients. Good dispensing practice procedures were not followed in all of the cases. The errors occurred at various stages of the dispensing process, including selecting the wrong product from the shelf; typing the wrong product into the computer; dispensing the incorrect strength; incorrect labelling; supplying expired medication; unauthorised generic substitution; incorrect recording of Schedule 8 products; and the inappropriate storage of Schedule 8 products. One complaint was caused by an extemporaneous compounding error.

**CATEGORY 2: INAPPROPRIATE SUPPLY OF A PHARMACIST ONLY MEDICINE**

Both cases in this category involved the inappropriate supply of a Pharmacist Only medicine (S3 medicine). The fact that these cases followed through to disciplinary action demonstrates the significance attached to the responsibility given to pharmacists in the supply of S3 medicines.

One case that involved the weight loss product Xenical® (orlistat) is of specific interest. The incident occurred in July 2004, only months after the down-scheduling of Xenical® from a prescription product to an S3 medicine by the National Drugs and Poisons Scheduling Committee (NDPSC). The registrant supplied the Xenical® to a 15-year-old girl without verifying her age. The supply was therefore outside the provisions of the *Health (Drugs and Poisons) Regulation 1996* (Qld), which specify a minimum age of 16 years for the supply of S3 products. The registrant also failed to follow the manufacturer’s recommended guidelines regarding the information to be gathered, and assessment of the patient’s body mass index (BMI) before supply takes place. Additionally, the registrant did not advise of any side effects.
CATEGORY 3: INAPPROPRIATE OWNER SUPERVISION

Three cases involved the responsibilities of pharmacy owners who were not necessarily working on-site in their pharmacies. As stated:

There was a failure by the registrant to ensure the pharmacy was adequately staffed on days of peak dispensing workloads. This is the third complaint received within three years about a serious dispensing error.

These cases make it clear that the responsibility of ownership extends to ensuring relevant protocols and procedures are in place in the pharmacy. Owners need to provide satisfactory proof to the Board if this function has been delegated to another pharmacist.

CATEGORY 4: EXCESSIVE SUPPLY OF PSEUDOEPHEDRINE

In all four 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.’

One case was determined by the Panel, one was referred to the Tribunal, and two were referred to the Tribunal following the imprisonment of the offenders. In the latter two cases the ground for disciplinary action was under Section 124(1)(i) of the Act, namely that the registrant had been convicted of an indictable offence.

The fact that pharmacists are imprisoned for the illegal supply of 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:

… 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.


and

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.


and

The seriousness of the breach of public trust was considered in sanctioning or ‘punishing’ the pharmacists:

….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.


SANCTIONS IMPOSED

In general, disciplinary bodies are able to apply a broader range of penalties that are more remedial than are those available to a court (Forbes, 2002). The Act specifies the sanctions to be imposed, namely: the Board or Committee may advise, caution or reprimand the registrant and enter into undertakings with registrants. The Panel or Tribunal may also impose conditions on the
registrant's registration. Additionally, registrants referred to the Tribunal may be suspended or have their registration cancelled.

Section 165 (2) outlines the sanctions the Board or Committee may impose:

(a) advise, caution or reprimand the registrant or require the registrant to attend, at a stated reasonable time and place, to be advised, cautioned or reprimanded;

(b) with the registrant’s agreement, enter into an undertaking with the registrant about the registrant’s professional conduct or practice.

Of the cases analysed the undertakings imposed by the Board included:

- That the sales of S2 and S3 medicines were to be in accordance with the PSA standards;
- Compliance with the elements of the QCPP and/or seek accreditation;
- Maintenance of membership of the PSA;
- Compliance with the provisions of the Health (Drugs and Poisons) Regulation 1996 (Qld);
- The employment of additional full-time equivalent pharmacists to current staff;
- Required proof of the Dispensing Protocols and Dispensing Errors and Complaints Protocols implemented;
- Successful completion of the Forensic Examination;
- Successful completion of the Essential CPE Weight Management module of the PSA;
- Successful completion of the PSA module on generic substitution;
- Required proof of a written procedure regarding the handling of controlled drugs;
- Allowing a representative from the Board to inspect the pharmacies in which the registrant was working to ensure compliance with the provisions of the Health (Drugs and Poisons) Regulation 1996 (Qld);
- Subscription to the PSA PriMED Pharmacy educational internet site; and
That medical sample packs of drugs would not be used when dispensing prescriptions.

Under Section 201 (2)(b) of the Act, a Panel or Tribunal may:

(b) impose conditions on the registrant’s registration, including for example, the following-
   (i) requiring the registrant not to carry out a type of practice or procedure;
   (ii) requiring the registrant not to provide services to a class of persons;
   (iii) requiring the registrant to carry out the registrant’s practice under supervision;
   (iv) requiring the registrant to undertake an educational course, or a continuing professional education activity, within a stated reasonable time and report to the registrant’s board after completing the course or activity;
   (v) requiring the registrant to obtain, and act on, advice from the registrant’s board or a stated person about the management of the registrant’s practice;
   (vi) requiring the registrant to report about particular aspects of the registrant’s practice to the registrant’s board or a stated person;
   (vii) requiring the registrant to report to the registrant’s board, within a stated reasonable time and in a stated reasonable way, about the registrant’s compliance with conditions imposed by the panel;

In these findings conditions imposed by the Panel or Tribunal included requiring the registrant to:

- Work under supervision of another pharmacist for a set period;
- Not own a pharmacy for a set period;
- Submit for a health assessment;
- Demonstrate competence to practise before being re-registered by the Board;
- Undertake the Australian College of Pharmacy Practice and Management modules Drug Abuse and Misuse 1 & 2 prior to re-registration to the Board; and
- Not resume practice for three years, provided psychiatrist evaluation is favourable.

Under Section 241 (2)(g) of the Act, the Tribunal may suspend a registrant’s registration for a stated time or, under sub-section (i), cancel the registrant’s registration. Registrants were suspended by the Tribunal for periods of
between nine months and two years, with various conditions imposed upon re-registration.

In deciding on the sanctions to be imposed, other information was considered as appropriate. This additional information could have been in favour of the registrant:

I accept that he is remorseful for what he has done. I also accept that these events have had a financial impact on himself and his family.

He is a man who is well regarded by those who know him and with whom he has worked and a number of references have been tendered in his support.

Or not in favour of the registrant:

From the information provided by Queensland Health, Mr *** had been subject to at least three inspections since 1991. On each occasion discrepancies were found in his controlled drugs register. In an inspection carried out in July 2003 discrepancies were found in seven different controlled drugs. Mr *** was unable to offer an explanation in any of those cases. He stated during an interview with Mr *** that he never undertook audits of his controlled drugs, he just assumed the register was correct……..Mr *** over a period covering at least 13 years, at best, shown a cavalier attitude to the management of controlled drugs in his possession.

The attitude of a registrant was also considered in determining a sanction:

The Board also took issue with Mr ****'s attitude to compliance with the accreditation standards of the QCPP and his lack of insight into the requirements of the QCPPs self-assessment process.

In two of the analysed cases it was evident the sanctions imposed were inconsistent as both cases seemed to indicate a deviation from the sanctions imposed in previous cases with similar facts.

One case involved the excessive supply of pseudoephedrine. The registrant in this case was required only to enter into undertakings with the Board, whereas all three registrants in the other pseudoephedrine cases had their registrations suspended for between nine months and two years. One explanation for the light sanction may have been the lack of evidence before the Board:
Although there is no direct evidence of either the supply of multiple packs of Sudafed 60mg 90s to a particular person, or the supply to particular people of Sudafed 60mg 90s at a frequency indicating that the usage was not therapeutically justifiable or was for non-therapeutic purposes, the purchasing records indicate a high level of sales, far higher than would normally be expected.

The other case that evidenced an inconsistent sanction involved the dispensing of Tramal SR® (tramadol) without directions. The patient in this case subsequently died of an overdose. Although the Committee identified the following errors, the registrant only received a reprimand:

1. The prescription for Tramal contained no directions about the use of Tramal or the dose to be taken or administered;
2. The customer *** was not the person the prescription was written for;
3. There was no evidence available to the registrant that *** had taken Tramal before; and
4. The Tramal prescribed was of the maximum available strength (200mg) the registrant failed to affix any label containing directions about the use of Tramal (including the dosage of Tramal to be taken) to the box of Tramal before providing it to ***

It can be argued that the purpose of disciplinary proceedings is neither to punish an offending health care practitioner (unlike criminal proceedings), nor to recompense the patient or the patient’s family who has suffered harm (unlike a tortious action). Accordingly, the patient outcome is not considered directly, as is the case with civil proceedings. However, part of the disciplinary process is to maintain appropriate standards within the profession and to maintain public confidence in health professionals, as specified in Section 123 of the Health Practitioners (Professional Standards) Act 1999 (Qld).

The pharmacist involved in this case made various errors in the dispensing of the Tramal SR® which were in breach of the Health (Drugs and Poisons) Regulation 1996 (Qld), as well as not following the endorsed professional standards. Additionally, the safety of tramadol had been questioned in various publications since registration in Australia in late 1998. Of specific relevance is an article published in the Australian Adverse Drug Reactions Bulletin (Adverse Drug Reactions Advisory Committee, 2003) in February 2003, just months before the incident. In the researcher’s opinion a reasonable pharmacist would have known about the safety risks at the stage of the incident, and should have been particularly careful in the dispensing of tramadol.
PATIENT CONTRIBUTION

In a civil negligence action the court may take into account the extent to which the plaintiff contributed to the adverse event or injury. In none of the disciplinary cases did the Board, Committee, Panel or Tribunal refer to any contribution to the event by the claimant. The absence of any discussion or reference to the contribution on the part of the patient was specifically noticeable in a case that involved a patient’s treatment being changed from methotrexate injections to methotrexate tablets. The patient’s specialist expressed surprise that the patient took the dose of the medication incorrectly: ‘She expressed surprise that Mrs *** had taken the tablets on a daily basis when she had always received the medicine weekly.’

In this case the specialist indicated the patient had previously been taking weekly tablets before being changed to weekly intramuscular injections. The specialist was therefore of the opinion that the patient should have known to take the tablets weekly. However, the patient took all of her other tablets on a daily basis, and: ‘…. assumed it would be one tablet daily as she took all her other tablets daily.’

Patients have various conceptions about medications, and in this case the patient might have thought the injection was more potent than the tablets. Hence, while a health professional may be of the opinion that a patient should be aware of certain information, patients should still be informed to eliminate confusion.

The approach not to assign any contributory responsibility to patients is in part a result of the absence of a Code of Health Rights and Responsibilities in Queensland. Although the Health Rights Commission Act 1991 (Qld) specifically required a code to be developed by the Health Rights Advisory Council within three years of the appointment of the Council in 1991 (Cahill, 1992), the Council didn’t progress this issue. However, in 2006 the development of a Code of Health Rights and Responsibilities was specifically
set as a priority by the then recently-appointed Health Quality and Complaints Commission (HCCC) under the *Health Quality and Complaints Commission Act 2006* (Qld).

**PRACTICE ISSUES IDENTIFIED**

Numerous themes relating to specific practice services, the registrants and system problems were identified during the analysis. This analysis is specifically useful, as it indicates those areas pharmacists should address in order to reduce their risk. The following are descriptions of themes identified through the qualitative analysis of the cases:

- Lack of appropriate advice
- Pharmacists’ knowledge base
- Procedures followed after mistake
- Pharmacy systems
- Other contributing factors

**LACK OF APPROPRIATE ADVICE**

In the majority of dispensing error cases, the pharmacist did not provide the required counselling according to the endorsed standards or Board policy. Had the basic counselling taken place, all errors would most probably have been identified. The appropriate counselling most likely would have prevented the incorrect dosing in the case where the patient was changed from methotrexate injections to methotrexate tablets without counselling: had the patient been counselled, she would have known how to use the medication, even though the label was not on the primary container:

As the primary container was not labelled (and the outer box discarded) Mrs *** started taking one tablet daily rather than two tablets weekly as has been prescribed.
This patient specifically qualified to have received counselling according to the endorsed guidelines: (1) the patient had a change in the dosage form of her medication; and (2) the medication has a narrow therapeutic index. Both of these factors are specific criteria when counselling should be offered to patients.

The disciplinary files had no reference as to whether the patients received CMI leaflets. It is assumed that if CMIs were provided, the pharmacists didn’t use them as counselling tools, as recommended in the endorsed guidelines (Pharmaceutical Society of Australia, 2006a, p. 369).

**Pharmacists’ Knowledge Base**

A consistent theme across the majority of the dispensing cases was the issue of the pharmacist’s knowledge base, which seemed to have been sub-standard. This is evident in the following extract, and demonstrates the pharmacist’s attitude towards the need for evidence-based continuing professional education:

Mr *** is not a member of the Pharmaceutical Society of Australia. He does not attend any formal continuing education programs. He attends drug company sponsoring evenings ‘… two or three times a year ….’ And occasionally reads the *Australian Pharmacist*.

A lack of current clinical knowledge significantly contributed to the dispensing errors in a number of the analysed cases. In dispensing a medication the pharmacist needs to use professional judgement and clinical knowledge in deciding when to confirm the prescribed medication with the patient and/or prescriber. It is therefore an objective decision that requires an adequate knowledge of both disease conditions and medication therapies. However, it seemed the types of medication or dosages involved in a number of the cases called for confirmation of the therapy with the patient and/or prescriber, which unfortunately didn’t take place:
Aldazine is an antipsychotic drug indicated for psychotic disorders unresponsive to at least 2 other antipsychotics. Its common adverse effects include sedation and anticholinergic reactions.

It is not known from the evidence given whether, in this particular case, the patient was a regular customer of the pharmacy. If the patient was a regular customer, it should have been more obvious that the Aldazine® was not the correct medication, as it is an antipsychotic used after other treatments have failed. It also has serious side-effects that warranted a discussion with the patient or carer to ascertain whether it was the correct product.

In another case, the pharmacist dispensed 100mg MS Contin® (morphine) instead of 10mg MS Contin® (morphine). It is the researcher’s opinion that a competent pharmacist would realise this was a very large dose that should only be used by patients who have been on long-term morphine therapy. Therefore, it seems this mistake was due not only to a selection error, but also insufficient clinical knowledge.

Lack of clinical knowledge also affected the way in which pharmacists handled the patients once a mistake had been identified – not realising the potential risks involved:

... while Mr *** (the pharmacist) was at the house he advised her that she would be able to drive to the doctors later that day (even though she could not remain standing when he was speaking to her) and return to work the following day.........

the advice provided to Ms *** by him seems unwise in the circumstances given that Ms *** was extremely drowsy at the time. Even if Mr *** was not aware of her drowsy state, the fact that she had taken a large dose of an antipsychotic medicine that she had not taken before and which commonly causing drowsiness and sedation should have alerted him to provide advice that erred on the side of caution......... in dealing with the dispensing error involving Ms *** he demonstrated a lack of adequate knowledge ...

**PROCEDURES FOLLOWED AFTER MISTAKE**

In only one case did the registrant comply with the recommended procedures in relation to a dispensing error as defined by Pharmaceutical Defence Limited (Pharmaceutical Defence Limited, 2005a). Although this case could have had serious consequences, the registrant acted quickly and hence avoided a
serious overdose with potential fatal consequences. Because of the pharmacist’s actions after the mistake was identified, the Board decided there was no ground for disciplinary action:

…although the registrant did mistakenly dose the patient with 625 mg instead of 125 mg of methadone as a syrup, his actions subsequent to the event complied with the accepted procedures to follow in the case of a dispensing error. In addition he went to considerable lengths to find the patient and resolve any problems resulting from the overdose despite receiving incorrect information from the patient himself.

A consistent reason why errors not resulting in serious harm to the patient formed the grounds for a complaint against the practitioner was due to the failure of the pharmacists concerned to manage the resolution of the error to the satisfaction of the complainant:

After contacting the Board for advice she contacted the same pharmacy on two further occasions requesting they come to the house and exchange the tablets. Eventually Mr *** came to the house and exchanged the tablets……….. no attempt was made by Mr *** to inform Ms ***’s doctors of the error.

The inappropriate management of mistakes had been raised in various Board communications (2005):

While the Board has raised these matters on a number of recent occasions, it is still receiving complaints where a formal complaint process either has not been followed or has been handled very badly. Complainants are often annoyed because of a perception of an arrogant or off-hand manner by the pharmacist and feel that their concerns have been neither appreciated nor acknowledged. As a result, matters that could have been resolved in a professional manner by the pharmacist become the subject of a Board investigation.

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 by the pharmacist. This causes patients to lose trust in the profession, as evident by one of the patients who stated in a letter to the Board:

…… will this happen to me again if I deal with the pharmacy? Why did it happen? Where are the checks and safeguards that professional organisations normally adopt? …. 
PHARMACY SYSTEMS

The primary cause of the errors in these cases was often associated with several elements that compounded the situation. The majority of the pharmacies involved in the disciplinary cases did not have adequate risk management processes in place. For example, double-checking during the dispensing process or the use of barcode scanners:

Despite a previous recommendation from the Board Mr *** had not implemented product barcode scanning technology. In this particular case the technology would have identified the error.

The adequate training of support staff in correct procedures was also identified as a problem:

Although everything should be checked by myself before leaving the dispensary, there were some instances where staff bypassed me and went straight to the customer.

Although there were protocols at the pharmacy whereby enquiries in respect of generic medication were to be handled by the pharmacist on duty at the time, the assistant didn’t follow the protocol.

OTHER CONTRIBUTING FACTORS

The data confirmed that the generic substitution was an issue. In one case the patient specifically indicated the substitution of a generic substance directly contributed to her confusion. This emphasises the important role pharmacists have in the counselling of patients when substitution has taken place:

She noticed the label underneath stated Aldazine 100 (thioridazine tablets) and assumed that she had been given a generic brand as she was always asked a question regarding dispensing a generic equivalent when presenting prescriptions at the pharmacy.

Similar packaging was identified by one registrant as contributing to the selection error:
The registrant said the two strengths of Dothep (25mg and 75mg) are packaged in the same size and shape box but are different colours.

**INCIDENTS REPORTED TO PHARMACEUTICAL DEFENCE LIMITED (QLD BRANCH)**

Table 4.3 is a summary of the incidents reported to Pharmaceutical Defence Limited (Qld branch) for the period 1 January to 5 December 2006. The total number of incidents reported to the Queensland office for the period was 85, a very small number considering it is estimated that more than 190 million prescriptions are dispensed by community pharmacies in Australia each year, of which 400,000 are thought to involve adverse events (Safety & Quality Council, 2002). Errors reported to PDL are usually from pharmacists and the Pharmacy Board of Victoria indicated that in Victoria this is three to four times the number reported to the Board (Marty, 2006).

The majority of reported incidents were selection errors (63.5%) that were either the incorrect strength or the incorrect medication selected, but with the prescribed item label.

Of specific interest are the five (5.9%) incidents classified as ‘Deficiency in advice to patient’, and the two (2.4%) incidents classified as ‘Adverse reaction to medication’. These two categories relate to the medication management role of pharmacists, and the fact that these incidents were reported indicates the shift in the role of pharmacists towards patient care.
Table 4.3: Pharmaceutical Defence Limited (Qld branch) incidents, 2006.

<table>
<thead>
<tr>
<th>Error classification</th>
<th>Number</th>
<th>Percentage %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect STRENGTH selected with prescribed item label</td>
<td>28</td>
<td>32.9</td>
</tr>
<tr>
<td>Incorrect MEDICATION selected with prescribed item label</td>
<td>26</td>
<td>30.6</td>
</tr>
<tr>
<td>Incorrect MEDICATION dispensed – prescription misread</td>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>Incorrect DIRECTIONS on label</td>
<td>5</td>
<td>5.9</td>
</tr>
<tr>
<td>WRONG PATIENT given prescription</td>
<td>3</td>
<td>3.5</td>
</tr>
<tr>
<td>DOSAGE error</td>
<td>4</td>
<td>4.7</td>
</tr>
<tr>
<td>OUT-OF-DATE item supplied</td>
<td>3</td>
<td>3.5</td>
</tr>
<tr>
<td>Incorrect FORM of medication dispensed</td>
<td>2</td>
<td>2.4</td>
</tr>
<tr>
<td>Incorrect PATIENT NAME on label</td>
<td>2</td>
<td>2.4</td>
</tr>
<tr>
<td>Deficient patient ADVICE</td>
<td>5</td>
<td>5.9</td>
</tr>
<tr>
<td>ADVERSE REACTION to medication</td>
<td>2</td>
<td>2.4</td>
</tr>
<tr>
<td>FORGED prescription detected</td>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>Webster pack error</td>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>Failure to dispense as per doctor’s instructions</td>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>Supply of ‘morning after’ pill to minor</td>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>TOTAL</td>
<td>85</td>
<td>100</td>
</tr>
</tbody>
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**SUMMARY**

The analysis of the disciplinary cases provided a wealth of information about the types of errors that lead to disciplinary action. The processes followed during disciplinary investigations provided insight into the approach the Board followed. However, the analysis of the evidence used indicated that endorsed practice standards and guidelines are not being used in a consistent way. The standard of proof applied throughout the cases was in accordance with the Australian tradition followed in disciplinary proceedings. The sanctions imposed overall seemed to be logical. However, two cases were identified as appearing to be
inconsistent with sanctions imposed in similar cases. Specific practice issues were identified through the case analysis that should be addressed in the development of risk management procedures. The Pharmaceutical Defence Limited (Qld branch) incident report statistics support previous research, which indicated a very small incident reporting rate. As discussed, two categories of the incidents specifically relate to the changed role of pharmacists towards patient care services.

4.3 ANALYSIS OF COMMUNITY PHARMACISTS’ PRACTICE

This section is an analysis of the semi-structured interviews with the 17 practising pharmacists, with the focus on their risk management strategies and the respondents’ knowledge of the need to develop risk management procedures. Participant information is followed by a description of the pharmacies and the types of services provided. This is followed by an analysis of pharmacy staff, focusing on their training levels, roles and continuous professional development. Identified practice themes, grouped under the following headings, are subsequently discussed:

- Patient familiarity;
- Practice processes and protocols;
- Pharmacy layout; and
- Practice realities.

This is followed by an analysis of the following core professional services offered:

- Supply of Over-The-Counter (OTC) products;
- Dispensing; and
- Monitoring and case detection.

Quotes which appeared to encapsulate the opinions of the majority of participants are included throughout the analysis to illustrate key points made.
PARTICIPANT INFORMATION

The participants’ ages varied between 24 years and 56 years. Fifteen participants qualified from the University of Queensland, which can be explained by the fact that, until recently, it had been the only South-East Queensland University offering pharmacy training. One participant qualified from Sydney University and one qualified overseas and completed the Australian Pharmacy Examining Committee (APEC) requirements to meet Australian registration requirements. In regard to pharmacy practice experience, four (23.5%) participants had less than five years experience, and six (35.3%) had more than 20 years experience. Table 4.4 provides a summary of participants’ years of practice experience.

Table 4.4: Interview participants’ experience in pharmacy practice.

<table>
<thead>
<tr>
<th>Years of practice</th>
<th>Number</th>
<th>Percentage %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-5</td>
<td>4</td>
<td>23.5%</td>
</tr>
<tr>
<td>6-10</td>
<td>2</td>
<td>11.8%</td>
</tr>
<tr>
<td>11-20</td>
<td>5</td>
<td>29.4%</td>
</tr>
<tr>
<td>&gt;20</td>
<td>6</td>
<td>35.3%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>17</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

Participants mainly had community pharmacy practice experience, with varying levels of management exposure. One participant had extensive experience in hospital pharmacy practice. Twelve (70.5%) participants were owner-managers, while five (29.4%) were managers only.

Fourteen (82%) participants had current membership with at least one of the following professional pharmacy organisations:

- Pharmaceutical Society of Australia (PSA);
- Pharmacy Guild of Australia (Guild);
- Society of Hospital Pharmacists of Australia (SHPA); or
Eight (47%) participants had membership with more than one of the organisations. Although mandatory continuous professional development was not compulsory in Queensland at the time of the interviews (Pharmacists Board of Queensland, 2007b), all of the participants indicated they were involved with some form of continuous education, whether it be attending educational sessions or reading journals:

I certainly read, read, read and make sure I do that on my own undertaking. I think that is essential and if certain articles are relevant or whatever I will make notes. P7

PHARMACY INFORMATION

Six pharmacies (35.3%) were part of a banner group, while 11 pharmacies (64.7%) were independent. In regard to the pharmacy categories:

- Five pharmacies (29.4%) were located next to a medical centre;
- Six pharmacies (35.3%) were located in a business street (of which one was a large discount-type pharmacy);
- Five pharmacies (29.4%) were situated in shopping centres; and
- One pharmacy (5.9%) serviced a private hospital as well as community patients.

PROFESSIONAL SERVICES OFFERED

Apart from dispensing and counselling, a wide range of professional services were offered at the pharmacies, including:

- blood pressure monitoring and advice;
- weight management advice;
- smoking cessation advice;
- nursing home care;
• Webster® and personal care packaging;
• dispensing of opioid substation therapies;
• Home Medicine Reviews (HMRs);
• blood glucose level interpretation and specialised diabetic counselling;
• equipment calibration, support and testing;
• equipment hire (e.g. baby scales, crutches);
• medication profiles;
• disease information; and
• patient specific extemporaneous compounding.

Services by a nurse specialising in child health were also provided on a regular basis at two of the pharmacies and one of the pharmacies offered consultations with a naturopath.

Decisions regarding which services to offer matched the pharmacies’ customer profile, and participants indicated they continuously evaluated the need to add new services:

…. we found it increasingly necessary to be able to offer that service otherwise patients were just drifting out of our pharmacy because we couldn’t do it for them. P17

We are trying to develop an incontinence practice where we are actually giving advice and assisting people with these sort of problems because that is a niche in our area. Primarily our patients are elderly people, from the lower socio-economic group … P10

Services offered were also a reflection of the pharmacists’ expertise and their interest areas. Overall, participants seemed to enjoy the services offered:

… It takes up a fair amount of time, but I find it very rewarding…. P12

A number of participants were frustrated by not being able to provide certain services that in their opinions should have been offered. Reasons given mostly involved financial, time and space constraints. Other barriers mentioned included the inability to become an agent of the National Diabetes Services
Scheme (NDSS)\textsuperscript{16}, and hence to supply free diabetes equipment to patients. This was due to the strict location rules applied by Diabetes Australia (Qld branch).

Staff employed to provide professional and medication supply services such as OTC sales and dispensing services included pharmacists, pharmacy support staff, pharmacy students (part-time) and pre-registration pharmacists.

The information gathered about the professional services offered in the pharmacies was mainly used for insight into the pharmacists’ approach towards the provision of these services and other extended services. It was, however, not within the scope of this research to investigate the risks associated with these services. This analysis, with regard to the provision of services, will therefore focus on contemporary core services, such as the dispensing of prescriptions, and the provision of patient advice.

**PHARMACY SUPPORT STAFF**

The majority of support staff either already had a Certificate 2 or Certificate 3 in Community Pharmacy qualification, or were in the process of undergoing training through the Guild (Qld branch) or PSA (NSW branch) to obtain the qualification. Of specific interest was the attitude of one manager who only employed support staff with a Certificate 3 qualification: all twelve of the support staff at this particular pharmacy therefore had a Certificate 3 qualification. One of the pharmacies had a pharmacy assistant with a Certificate 4 in Community Pharmacy qualification. Three participants indicated they employed support staff with extensive years of pharmacy experience but who were not interested in gaining a formal qualification. However, participants overwhelmingly indicated that in the future they were aiming to only appoint new staff members

\textsuperscript{16} The National Diabetes Services Scheme (NDSS) is a Commonwealth program that provides blood and urine testing strips and consumables for special injection systems at subsidised prices to people who register for its benefits. In addition to this, all state and territory governments have agreed to fund the co-payments for needles and syringes thus making them free for all NDSS registrants. Diabetes Australia administers the NDSS for the Commonwealth.
with a suitable formal qualification, or who would agree to undertake the recommended training:

We undertook an in principle decision probably about two years ago that any new employees that were going to join the organisation it would be mandatory within two years of commencing employment to attain Certificate 2 training. P17

Managers supported staff through time-off to undergo training, and some of the managers also contributed financially to staff training. Various other strategies were employed to train new staff, which included formal induction programs and ‘buddying’ an inexperienced staff member up with another, more experienced staff member.

In accordance with the Pharmacists Board of Queensland guidelines and policy regarding dispensary assistants (Pharmacists Board of Queensland, 2007b), all the participants indicated they only allowed support staff with a Certificate 3 qualification or those who were enrolled in a Certificate 3 training program to assist in the dispensary. However, the way in which participants utilised dispensary assistants and the functions delegated to them varied considerably.

Although the Board guidelines specify that the counselling of patients should be performed by pharmacists, only four of the pharmacists interviewed clearly indicated this function was reserved mostly for pharmacists. The majority of participants did not have specific position descriptions in place, and did not use dispensary assistants in a way that freed up pharmacists to provide patient care services, but instead delegated the counselling function to dispensary assistants. Three participants did not provide a clear differentiation between pharmacists’ activities and assistant activities in the dispensary. Assistants, therefore, seemed to be utilised to undertake exactly the same activities as pharmacists, apart from a pharmacist always undertaking the legally required final check in the dispensing process. Accordingly, roles were determined by the workload at a specific point in time, and the use of assistants did not necessarily free pharmacists to provide value-added patient care services:

It really just depends on the demand. If it’s busy then I am faster on the computers so I will actually do all of the dispensing and if I need to talk to the
customer I communicate with coloured tags........ I guess the role is shared. Because we are only a small store the girls are capable of dispensing, they are capable of serving on the counter as am I, so it really just depends on how, what the demand is. P13

They all put the information into the computer, they select the products, put the labels on and then I check it. I still do a lot of dispensing myself but if I am too busy they will do that. P11

This lack of planning to use assistants for technical functions is of particular concern, as it seemed the majority of pharmacists remain in the dispensary to perform technical functions while the dispensary assistants perform the professional patient care functions.

On the other hand, as previously stated, a small percentage of participants had dispensing processes in place that enabled pharmacists to spend more time with patients:

So they do a lot of the data entry and that sort of frees us up to counsel people with the prescriptions, we try to be very focussed about giving good customer service. My people keep coming back to us I hope, so we try to give them the best advice we can, so having the techs doing the data entry frees us up........If we are tied up with those sort of clients or if we counselling someone already, the techs will just step in straight away and continue data entry. We try to get them in the habit of doing a lot of the data entry and labelling so that then does free the pharmacist up. P10

Although the majority of respondents indicated they delegated only specific functions involved with the dispensing process to assistants, there was a large degree of variation between the different pharmacies in regard to the type of functions that were delegated. For example: some respondents preferred pharmacists to enter the data and preferred the product selection and labelling to be done by assistants, while others preferred it the other way around. Therefore, no consistent pattern was identified, and the delegated functions were often a reflection of a specific pharmacist's personal preference.

Participants indicated they use their discretion in allocating tasks to the different dispensing assistants. Issues considered included assistants' level of expertise and accuracy:
Yes, everyone gets a turn because we don’t want them to lose their dispensing ability. But some of them are more involved in the dispensary than others. Some will purely only dispense, some of them will help me with claims, some of them will order and one of them Webster packs. So they differ in their extent that I let them be involved in the dispensary…. the ones that I believe are extra good then help me a bit more than the ones that I think are a little lesser. P16

Two participants indicated the dispensing functions delegated to assistants depended on the type of dispensing services provided: for example, they do not use assistants in the dispensing of nursing home or hospital inpatients, but for other dispensing purposes:

With the nursing home it is usually I who put things through the computer because I can keep a track of the history and timing and you know what is going on with the scripts. P12

None of our non-pharmacists dispense for the hospital because that involves assessing medication charts for the most part ….. P8

STUDENTS AND PRE-REGISTRATION PHARMACISTS

The employment of pharmacy students provided pharmacists with various advantages, such as having ‘support’ staff with a solid academic background and assisting pharmacists in keeping their academic knowledge up-to-date. It also provided pharmacists with the opportunity to access electronic information resources not generally available in pharmacies:

… some of the stores also have Micromedics. Students get it for free. It’s a good product. It is very expensive but when the students are here we jump on. They have a logon. P3

Those participants who employed pre-registration pharmacists indicated they were focused on providing a proper teaching environment:

Because we constantly have a pre-reg here I would say we are pretty much spot on. They keep you on your toes. P8

.... we always like to research anyway because we are in a teaching environment so the very fact that we have a pre-registration pharmacist, even if we know the answer, we would like to point out where we would have found it if we didn’t know it. P17
Pharmacists who employed pharmacy students or pre-registration pharmacists stated they had additional motivation to ensure their practice knowledge was current. Thus, the employment of pharmacy students and pre-registration pharmacists provided various additional advantages to pharmacists.

**Patient familiarity**

Some participants said there was a direct link between their knowledge of patients and the quality of the services they were able to provide:

> Because I've been here for so long too I have a pretty good knowledge of the meds that my patients are on …. so I guess to me then it makes it a lot easier to do the job that I do because I can say that Mrs So & So aren't you on this and I can check and sure enough she is. P16

Knowing their patients' medication histories not only provided pharmacists with a good basis of information to counsel patients, but also reduced the risk of errors due to incorrect selection of medication, especially for those patients on chronic medication. Participants also indicated it reduced the risk of clinically significant drug interactions both with prescribed medications and OTC therapies.

> Probably a good part of the system … is that we have the consistency in our staffing and people know us well and we get to know people well. We have time to speak to people and you know we have the availability of the pharmacist. P14

Participants from pharmacies that serviced local suburbs/communities all indicated they knew most of their patients’ medication histories. The pharmacists from the suburban pharmacies were of the opinion they were more likely than those from the the bigger shopping centre pharmacies to form a relationship with their customers, and hence become familiar with patients' medication histories.
PRACTICE PROCESSES AND PROTOCOLS

Participants all indicated having processes and procedures for the various professional services in place, although only the minority of participants had these in written format. Sixteen of the 17 pharmacies were accredited under the QCPP. However, the majority of pharmacies seemed to only use the templates for reaccreditation purposes and did not integrate it with daily practice procedures. It therefore seemed that many respondents did not realise the potential risk management focus of the program. Although the majority of participants did not use the program templates and recommended processes continuously, the program did create an awareness of the need to have standard operating procedures in place. However, the procedures were not used all the time.

Overall, participants had a poor knowledge of the criteria involved in the Professional Practice Standards, with only two participants being familiar with the Pharmacists Board of Queensland policies and guidelines. On the other hand, all participants were familiar with the Standards for the provision of Pharmacy Medicines and Pharmacist Only Medicines in Community Pharmacy (S2/S3 Standards).

The majority of participants did not keep any record of instances when CMI leaflets or other counselling tools were used or issued. Overall, intervention record keeping was uncommon, especially detailed recording. Only three participants indicated they made electronic or other notes, such as reminders to ask follow-up questions. However, due to time constraints, these three participants did not keep notes on a regular basis:

Whether it needs to be recorded? Where do you draw the line? Do you do it for all? That creates so much red tape. I think that comes down to personal discretion, that comes back to being a pharmacist. You need to decide for you own self if you have been educated well enough to look at that and discreetly say I’ve spoken with Mr Smith about this Ibuprofen – I should make a note about that we have spoken about it and do that off your own. P7
None of the respondents kept a record of near misses. In general, respondents recorded actual medication errors, although some respondents only recorded errors when they filed an incident report with their professional indemnity insurer (e.g. Guild Insurance), as those instances were considered of a more serious nature, and they feared potential litigation.

All of the participants implemented systems in the dispensaries to manage and reduce the risk of picking or selection errors. The methods varied, but mainly involved the separation of strengths on the shelves in those instances of boxes that looked similar; turning certain boxes upside down to serve as a mental reminder; highlighting shelf labels to remind staff of potential selection errors; or relocating a specific medication to another area of the dispensary.

**Pharmacy Design**

The design of a pharmacy, and specifically the layout of the dispensary and counselling areas, is an important component of risk management in regard to the provision of professional services. Although not all of the interviews took place at the pharmacies and the aim was not to inspect pharmacies for good practice criteria (such as appropriate lighting and the reduction of distractions that can lead to errors), a variety of design and layout issues relating to risk management were identified through participants’ comments.

Participants were well aware of the forward dispensing pharmacy model, that aims to integrate the pharmacist with the patient at the outset and at the conclusion of the dispensing process. Approximately half of the pharmacies used a model that seemed to be in between the forward pharmacy dispensing model and the traditional dispensary model. That is, the support staff received the prescriptions from the customers but promoted a pharmacist being involved with the counselling of the patient/carer. The design of the pharmacy was related to the type of pharmacy, and the design limitations of a shopping centre pharmacy were specifically highlighted by one of the participants as being a practice barrier:
Our pharmacy is probably designed to look like most other shopping centre style pharmacies in Australia where we have cash registers on the primary counter and we have a small consulting area, sit down desk area which is certainly well utilised but to be honest 80-90% of patients receiving prescriptions are still receiving that at the point of sale where there is a cash register and other business activities taking place so I see it as a limitation to be able to provide a high level of counselling and intimacy. Like I said we still have sit down counselling areas which are utilised but it’s not appropriate to do that for every single patient. Sometimes counselling should be kept to a shorter period of time …. I just dislike the physical setup. I think that is just part of Australian culture at the moment. P17

This comment indicates that many issues need to be considered in the design of a pharmacy, including what customers are used to. Therefore, any move by a pharmacist to change the pharmacy layout to promote patient care services would require very careful planning and marketing. The position of the counselling area was identified by one of the participants as a very important factor in the provision of quality services and the ability of the pharmacist to intervene when support staff counselled patients:

As I am in close proximity I can hear any conversation. I really believe I am very involved in every transaction…I can see and hear and have that interaction. I try not to interrupt, but if I can see or hear a potential error – which is few and far between, if it’s probably minor I will deal with it later and say we should have done it this way or that way. P7

Therefore, it was the perception of this pharmacist that, regardless of the size of a pharmacy, it is important that the counselling area be designed in such a way that a pharmacist in the dispensary can overhear conversations. Participants from the smaller type suburban pharmacies indicated they specifically preferred their smaller type of pharmacies to larger pharmacies, as they have more time to provide patient care services.

One pharmacy provided extensive dispensing of opioid substitutes for the treatment of heroin addiction patients. This pharmacy had a separate room at the back of the dispensary with thick glass in between the pharmacist and clients to improve security, to separate the opioid patients from general customers, and to provide privacy to the opioid patients, as the room is not visible from the front of the pharmacy. Two participants had separate consulting rooms, although the one participant indicated that the room was only for use by a naturopath. The other participant had just renovated the pharmacy
to create the consulting room, and planned to specifically provide pharmacist counselling and speciality services:

It gives us a lot of opportunity. It is a matter of working and building on it and we can quite easily have a baby nurse come in, we could do glucose testing or cholesterol testing in there if we wanted to .... Not particularly big but it’s big enough to have a desk, two people and some extra equipment and it gives us an opportunity to try and expand our services a little bit, to make a difference. P10

SUPPLY OF OVER-THE-COUNTER (OTC) MEDICINES

There was a huge degree of variation between pharmacies regarding the management of OTC medicines. This inconsistency specifically involved the quality of service provided, and the involvement of pharmacists in the supply of these products. Processes varied, and the majority of pharmacies allocated this function to support staff. Participants expressed overall confidence in their staff to handle the supply of OTC products:

They all understand, I hope and I believe they understand the limits of what they can assist with. If the patient hasn’t had the product before, if they have used the product and it’s not working, if they are on other medications that may potentially interact with what they are requesting or if they have some sort of uncertainty about the condition or about the request they will then actually ask for the pharmacist and they are really quite happy to do that and we encourage that because they are very well trained and they are senior and they will often know the answer to the issue anyway because of their years in pharmacy but they still have a good understanding of when to refer to the pharmacist or request the pharmacist’s advice. P10

Although the trust in support staff to supply OTC medicines allowed pharmacists to focus on other services, it was of concern that only a few participants indicated that they provided ongoing, continuous, structured training to their support staff to ensure they received evidence-based information about different products. One participant specifically allocated a pharmacist or a pre-registration student to the OTC and counselling counter.

Participants indicated that the PSA ‘What-Stop-Go’ protocol for providing Pharmacy medicines and Pharmacist Only medicines (Pharmaceutical Society of Australia, 2005b) was used by staff as a tool for referring customers to the
pharmacist. Only five participants (29.4%) indicated that staff also used various other criteria and a variety of customer prompts to assist in deciding when to refer customers to a pharmacist.

Although participants indicated that staff used the ‘What-Stop-Go’ protocol, approximately half of the respondents did not seem to have a well-defined quality system in place and support staff referred patients on an *ad hoc* and unstructured basis:

*Anything they are not sure of…”* P11 and “*Well I guess the rule is if they are not sure about anything they have always got to ask.*” P13 and “*If they get stuck with anything they refer them to me.*” P6

Therefore, despite the many initiatives implemented by the professional organisations and the development of the Standards for the Provision of Pharmacy Medicines and Pharmacist Only Medicines in Community Pharmacy (S2/S3 Standards), a large percentage of pharmacies still did not implement clear guidelines. This fact is alarming, as the absence of procedures not only impacts on the quality of the service provided by the pharmacies, but is also a risk to all pharmacists who supervise support staff in those pharmacies.

With regard to the sale of S3 medicines, all participants reported some pharmacist involvement in the selling, in accordance with the requirements of the *Health (Drugs and Poisons) Regulation 1996* (Qld). However, the level of involvement varied considerably. For example, some pharmacies had forms with basic questions to be completed by support staff, which were given to the pharmacist to verify that the S3 medicine supply was therapeutically justified. In those instances pharmacists provided very limited input regarding the appropriateness of the supply:

*Obviously they run it all past me but given that we are so busy I often don't have the time to go and individually see every S3 patient, so if I can see on their history that they have had it before which a lot of them do …………. it is a matter of OK, I have spoken to them before about so, I just say here we go.* P16

In general, the quality of the service in regard to the supply of OTC medicines varied considerably between pharmacies. The majority of participants did not
regard this as a pharmacist’s direct responsibility, and pharmacists were mostly involved only when support staff identified that the supply required a pharmacist’s intervention.

**DISPENSING**

Most participants made use of the Pharmaceutical Defence Limited (PDL) ‘Guide to good dispensing’ (Pharmaceutical Defence Limited, 2005b) as a dispensing and training guide, and had it displayed in the dispensary. In contrast, the Professional Practice Standard for dispensing was not known by the majority of participants and not used to develop practice processes. As mentioned previously, most participants used dispensary assistants. However, the majority of participants didn’t have clear procedures regarding those functions that should be carried out by dispensary assistants and those that should be carried out by pharmacists, apart from the final check by the pharmacist.

A huge difference existed in the importance placed on workflow, with some participants not mentioning workflow at all during the interview, while others indicated that they regularly review the workflow environment to ensure it delivered maximum efficiency:

> We have a protocol as well. We start from the left of the bench ……… the script will start on the left. We have a working regime, left to right. It comes through, label on the script then check both scripts. *** will check them, then I will check them and put them in the box and then they get checked again either by myself, *** or ***. They basically get triple checked, but under no circumstances do the scripts sitting on that bench go out. That’s our simple check. P7

Those participants who used barcode scanners were of the opinion that it did reduce error rates. On the other hand, participants who didn’t use scanners were of the opinion that scanners were of limited value, as their use does not detect errors due to incorrect data entry.

All participants used plastic baskets to store dispensed medication, and three participants indicated they used communication tools such as colour cards in
the trays to communicate information to support staff; for example, that the patient has to be counselled by a pharmacist or given specific information about recommended storage conditions. One participant indicated the pharmacy had a protocol requiring a final check by a pharmacist at the time of supplying the medication to the patient or their agent:

Our whole process is probably a little bit frustrating from the patients' point of view ….. when a prescription is dispensed, checked, put around in the bay for collection then when the patient comes and it’s requested it doesn’t just get given to them, the assistant must bring it back to the pharmacist again for another check prior to it going out. Yes it is something we can’t not do. I have done it for 10 years now. I know it’s slow, I know other pharmacists find it extremely frustrating to have to do that but it provides two important areas. It addresses one certainly there’s an extra check there, I must admit the check then is kept pretty brief for obvious reasons we can’t redo the whole prescription again. The other thing it allows us to do is whether at that point in time relay to the assistant who is handing out the medication anything that we feel might be pertinent or relevant to make special mention of if we weren’t going to counsel personally in that situation. But that is certainly an excellent way of detecting errors that haven’t been picked up yet. Slow but extremely important. I could not do it any other way now. P17

The degree of direct pharmacist contact with patients with regard to dispensed medication varied considerably between the participants, and the majority of participants counsel patients only when it is a medication they haven’t had before. Participants indicated they frequently need to use professional judgement in dispensing activities. Some participants indicated they aim to judge patients’ prior knowledge and attitudes in determining the level of counselling to be provided, the member of staff who should provide the counselling, and the depth of information to be provided about potential side-effects:

I mean you have to watch if they are the sort of person who will get every side effect if you tell them its possible, then they will get it, so you might not tell them too much......... It’s professional judgement, we try not to scare them off. P12

Participants also indicated that pharmacist involvement in patient counselling is often based on the complexity of the prescribed medication and the availability of the pharmacist.
Participants used different criteria regarding the supply of CMI leaflets. Only one participant indicated it was part of the pharmacy protocol to ask the patient when the prescription was handed in if they would like to get written information. One participant indicated they took into consideration prescribers’ preferences in issuing CMI leaflets as certain specialists preferred that it not be offered to their patients. The current CMI format and lack of quantifying side-effects were specifically raised by one participant as a major concern and a reason to withhold certain CMIs.

In general, a large degree of variation existed between participants in regard to dispensing processes and the involvement of pharmacists in the provision of patient counselling.

**MONITORING AND CASE DETECTION**

The level of monitoring services offered varied; for example, some participants provided blood pressure measurement services with limited advice and recording, whereas others provided an in-depth, time-consuming service:

> ... certainly we take their details, record it, keep it on file. Trained staff may be able to assist with that part of the process. The interpretation of the results is always done by a pharmacist and at that point in time we supply written information and verbal advice in interpreting results as well as other things like fat, carb and other ongoing stuff for them to learn a bit about maintaining normal blood pressure. P17

Although only one participant had specific concerns about the legal implications regarding blood pressure monitoring, these risks would apply to all pharmacists offering this service:

> I try to stick to the basics. I’m a bit concerned with the legalities and problems with blood pressure management. If we advise someone that their blood pressure is OK and the next thing we know they are in hospital with a heart attack. Some sort of legal case, poorly managed by you. I’m not too sure of the legal ramifications there. I’m a bit concerned about that. I am not qualified to work the machines. I try to stay away from that. P7
Blood glucose monitoring services provided were focused mainly on the advising of patients about the correct use of equipment and the interpretation of results. Of interest is the fact that only one respondent provided blood glucose testing, and only provided the service on request by patients. Many participants provide services free-of-charge, but would prefer to be remunerated; and one participant specifically commented that their experience was that patients value a service more if they have to pay for it.

**Summary**

The interview analysis provided a wealth of information about community pharmacy practice in the context of risk management procedures implemented to provide professional services. The interviewed pharmacists offered a range of professional services, however, very few pharmacists had written procedures and protocols in place. Although pharmacy support staff were said to be well trained overall, most participants did not utilise support staff in a way that released pharmacists to provide patient care services. Instead, many of the patient care services were provided by support staff and were therefore provided at a very basic level.
4.4 COMPARISON OF REGULATORY REQUIREMENTS

This section presents the findings related to the legislative provisions that provide for the regulation of the pharmacy profession in the various states and territories. A general description of the regulatory role is followed by a description and critique of the examined regulatory differences. The focus is on the legislation as in place at the end of 2006, with some reference to changes to be promulgated or introduced throughout 2007.

Analysis of the data is presented under the following headings:

- The legislative framework;
- Conduct warranting disciplinary action;
- Practice standards, policies and guidelines;
- Pharmacist annual registration requirements;
- Pre-registration pharmacist training and registration requirements;
- Registers; and
- Pharmacy premises and equipment requirements.

REGULATORY VERSUS PROFESSIONAL ROLES

Pharmacy registering authorities maintain a register of pharmacists; approve pharmacy premises in most jurisdictions; oversee the training of pre-registration pharmacists; and ensure that professional standards are maintained, with pharmacists failing to meet the standards being disciplined. The administrative costs of the authorities are financed through registration fees.

The jurisdictions operate under different regulatory models, with specific differences in regard to the roles of the registering authorities and the roles of the professional organisations. The Western Australia registering authority, the Pharmaceutical Council of Western Australia, has the dual role of also
managing the professional organisation, the Pharmaceutical Society of Western Australia.

The other jurisdictions departed from the English precedent of having one body responsible for both professional regulation and being the advocate of the profession. However, the extent to which the professional organisations are involved in regulatory functions varies considerably between jurisdictions. The jurisdictions also differ in regard to the way they incorporate practice standards developed by the professional organisations, and in the degree of stakeholder regulation.

**THE LEGISLATIVE FRAMEWORK**

Table 4.5 lists the eight pharmacy registering authorities with the legislation in place that provides for the establishment of the authorities, the registration of pharmacists and the management of complaints, investigations and disciplinary processes.

The Australian Capital Territory and Northern Territory are different from the other jurisdictions in that one Act in each of these jurisdictions provides for the registration and discipline of all health professionals. In Victoria the *Health Professions Registration Act 2005* (Vic), which came into force on 1 July 2007, similarly resulted in all health professions coming under a single Act. Queensland provisions dealing with the discipline of registrants have been separated from the legislation dealing with the registration of pharmacists. The *Health Practitioner (Professional Standards) Act 1999* (Qld) deals with the discipline of all health professionals, except nurses, in Queensland. The objective of dealing with all health professionals with one piece of legislation is to improve consistency across disciplines with regard to disciplinary processes and outcomes.
Table 4.5: Pharmacy regulation legislation.

<table>
<thead>
<tr>
<th>Authority</th>
<th>Legislation providing for establishment of authority</th>
<th>Legislation specifying disciplinary process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists Board of Queensland</td>
<td>Pharmacists Registration Act 2001 (Qld)</td>
<td>Health Practitioner (Professional Standards) Act 1999 (Qld)</td>
</tr>
<tr>
<td>Pharmacy Board of New South Wales</td>
<td>Pharmacy Act 1964 (NSW) Pharmacy Practice Act 2006 (NSW) to commence on a date to be specified</td>
<td>Pharmacy Act 1964 (NSW)</td>
</tr>
<tr>
<td>Pharmacy Board of Victoria</td>
<td>Pharmacy Practice Act 2004 (Vic) was replaced with Health Professions Registration Act 2005 (Vic) on 1 July 2007</td>
<td>Health Professions Registration Act 2005 (Vic)</td>
</tr>
<tr>
<td>Pharmacy Board of South Australia</td>
<td>Pharmacists Act 1991 (SA) Pharmacy practice Act 2007 (SA) to commence later in 2007 or 2008</td>
<td>Pharmacists Act 1991 (SA)</td>
</tr>
<tr>
<td>Pharmacy Board of Tasmania</td>
<td>Pharmacists Registration Act 2001 (Tas)</td>
<td>Pharmacists Registration Act 2001 (Tas)</td>
</tr>
<tr>
<td>Pharmaceutical Council of Western Australia</td>
<td>Pharmacy Act 1964 (WA) Pharmacists Bill 2006 (WA) expecting to be submitted to Parliament in August 2007</td>
<td>Pharmacy Act 1964 (WA)</td>
</tr>
<tr>
<td>Pharmacy Board of the Australian Capital Territory</td>
<td>Health Professionals Act 2004 (ACT)</td>
<td>Health Professionals Act 2004 (ACT)</td>
</tr>
<tr>
<td>Pharmacy Board of the Northern Territory</td>
<td>Health Practitioners Act 2004 (NT)</td>
<td>Health Practitioners Act 2004 (NT)</td>
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</table>
In addition to the disciplinary processes followed by the registering authorities, there are also health complaints commissions in every state and territory, which handle service complaints. The establishment of these commissions occurred as part of a general move towards the recognition of greater consumer rights internationally (Wilson, 2006). Complaints are managed between the relevant commission and registration board, and are dealt with depending on the nature of the complaint.

**Board membership**

The Acts *inter alia* prescribe the membership of the various pharmacy registering authorities. In all seven jurisdictions that have boards in place, the majority of members must be pharmacists who are either (1) nominated, elected and/or appointed by the registrants and/or professional organisations and universities; or (2) appointed by Governors/Ministers. Membership of all boards include community representation. The Pharmaceutical Council of Western Australia, being the professional organisation, consists of elected pharmacists only.

**Conduct warranting disciplinary action**

The provisions in the legislation in each of the jurisdictions that identify the conduct or behaviour of a pharmacist that will generate disciplinary proceedings are not uniform. The types of categories of conduct that will constitute a complaint are defined with terms such as ‘professional misconduct, unprofessional conduct, carelessness, incompetence, impropriety, misconduct or infamous conduct in a professional respect’. In New South Wales, 'professional misconduct' is defined as (section 19A of the *Pharmacy Act 1964* (NSW)):

(a) any conduct that demonstrates a lack of adequate:
   (i) knowledge;
   (ii) experience;
(iii) skill;
(iv) judgement; or
(v) care.

This definition of ‘professional misconduct’ differs significantly from the Queensland definition. The Queensland definition of ‘unsatisfactory professional conduct’ as defined in Section 4.2 is, however, very similar to the Victorian definition of ‘unprofessional conduct’ (section 3 of Health Professions Registration Act 2005 Vic):

(a) conduct of a health practitioner occurring in connection with the practice of the practitioner's health profession that is of a lesser standard than a member of the public or the health practitioner's peers are entitled to expect of a reasonably competent health practitioner of that kind;
(b) professional performance which is of a lesser standard than that which the registered health practitioner's peers might reasonably expect of a registered health practitioner;
(c) infamous conduct in a professional respect;
(d) providing a person with health services of a kind that are excessive, unnecessary or not reasonably required for that person's well-being;
(e) influencing or attempting to influence the provision of health services in such a way that client care may be compromised;
(f) a contravention of section 94 or the guidelines issued under section 95;
(g) the failure to act as a health practitioner when required under an Act or regulations to do so;

............

(j) in the case of a registered pharmacist, if the pharmacist owns or has a proprietary interest in a pharmacy business approved under Part 6, failure to comply with a condition of approval of that pharmacy business;

(k) the breach of an agreement made under this Act between a health practitioner and the responsible board that registered that practitioner.

In contrast, South Australia defines ‘unprofessional conduct’ (from Codes of Professional Conduct and Professional Practice) as:

1. Improper or unethical conduct in relation to professional practice; and
2. Incompetence or negligence in relation to the provision of pharmacy services; and
3. A contravention of or a failure to comply with –
   (a) a provision of the Act; or
   (b) a code of conduct or professional standard prepared or endorsed by PBSA under the Act; and
4. Conduct that constitutes an offence punishable by imprisonment for 1 year or more under some other Act or law; and
5. Any failure to meet the requirements of professional duty and/or responsibility or the abuse of the privileges and opportunities afforded by practising as a pharmacist.
There is therefore a degree of inconsistency in regard to the terms used, as well as different meanings assigned to similar terms.

The jurisdictions have similar step-wise processes in place whereby less serious breaches are streamlined and the more serious breaches are referred to committees or panels. A significant difference exists between the powers of the various authorities to impose sanctions; for example, in Queensland, Western Australia and the ACT, the cancellation or suspension of registration is reserved for Tribunals. The new Victorian and New South Wales legislation to come into effect in the near future will similarly strip those Boards of the power to suspend or deregister practitioners. In comparison, the Pharmacy Boards of South Australia, Tasmania and the Northern Territory have the power both to suspend registrations for up to three years, and to cancel registrations.

New South Wales is the only jurisdiction that makes public all disciplinary case outcomes, and all disciplinary decisions since 1990 are published at the AustLII website, a public-accessible website with legislative data that is jointly operated by the University of New South Wales and the University of Technology, Sydney. The other jurisdictions only publish the more serious outcomes, namely suspension of registration or cancellation, in detail to registrants whereas less serious sanctions are de-identified in newsletters and bulletins.

**PRACTICE STANDARDS AND GUIDELINES**

All registering authorities have the mandate of ensuring that practice standards are maintained, and hence to discipline those who fail to meet these standards. The Pharmaceutical Society Code of Professional Conduct had been adopted, either formally or informally, by all jurisdictions. There is therefore an overall expectation that the Code underpins all activities performed by pharmacists throughout Australia.

All registering authorities, except the Pharmaceutical Council of Western Australia, had a role in the setting of standards. The professional standards developed by the professional organisations had been incorporated into the
authorities’ policies with various levels of integration. Different terminology was used to describe the various levels of integration. With regard to the Professional Practice Standards and S2/S3 Standards, jurisdictions either: (1) endorsed the Standards; (2) adopted the Standards; or (3) referred to the Standards in Board publications without formally adopting the Standards.

Findings about exactly what these different levels implied, and the extent to which the various authorities used the Standards in the administration of their functions and in disciplinary procedures, were not clear. Queensland, the ACT and the Northern Territory officially endorsed all the professional standards (including the Professional Practice Standards and the S2/S3 Standards) and guidelines published in the Australian Pharmaceutical Formulary. New South Wales and Western Australia did not formally adopt the standards but, from time to time, referred to selected standards and guidelines in Board publications. In contrast, Victoria, South Australia and Tasmania formally adopted all of the standards and guidelines. Thus a difference exists in the extent to which the various authorities use the standards in the administration of their functions, the determination of professional standards for their members, and as admissible evidence in disciplinary procedures.

There was some degree of overlap with the standards and guidelines endorsed and/or adopted and certain of the authorities’ developed standards and guidelines; this was particularly evident in Queensland. Various authorities also developed policies and guidelines relating specifically to their jurisdictions; for example, the use of pharmacy support staff and advertising guidelines.

Individual practitioner professional indemnity insurance was mandatory in Victoria, South Australia, Tasmania, the ACT and New South Wales, while the other jurisdictions recommended only that members have individual insurance. The QCPP had been ‘endorsed’ by Queensland, ‘recognised’ by Victoria, and ‘supported’ by South Australia and the ACT.

The practice resources developed by the various authorities varied considerably. The Pharmacy Board of Victoria had taken a very pro-active
approach and developed the ‘Guide to the legal and practical aspects of pharmacy’, a comprehensive reference guide summarising legislative requirements and expanding on the Board’s practice requirements. The Pharmacy Board of South Australia has a ‘Code of professional conduct and professional and professional practice’ which summarises the Board’s requirements, and similarly the Pharmacy Board of Tasmania has a ‘Pharmacy Code’. The Pharmacists Board of Queensland developed a ‘Registrants’ Resource Kit’ in 2007 with the Board’s policies and guidelines.

**PHARMACY OWNERSHIP, PREMISES AND EQUIPMENT REQUIREMENTS**

Except for certain grandfather clauses, community pharmacy ownership is restricted to pharmacists in all of the jurisdictions. Provisions exist in all of the jurisdictions to enable friendly societies to own pharmacies, except the ACT. Provisions in certain jurisdictions also provide for relatives of a pharmacist to have shares in a pharmacy (*Pharmacists Registration Act 2001* (Qld) at section 139A and ACT Pharmacy Board Statement 18: Incorporated pharmacies at Company directors and members). The Northern Territory legislation provides for Aboriginal health services to own pharmacies (*Health Practitioners Act 2004* (NT) at Schedule 8). The number of pharmacies a pharmacist can own or co-own varies between the jurisdictions with no restrictions in the two territories, Western Australia only allowing two, Tasmania and South Australia four whilst the other states allow five per pharmacist.

Pharmacy premises need to be registered in New South Wales, Victoria, South Australia, Tasmania and Western Australia. The other three jurisdictions do not require premises registration, and are therefore limited in their level of control over pharmacy premises and the ability to address deficiencies. Pharmacy inspection schedules are followed only in New South Wales, Victoria, South Australia and Western Australia. New South Wales conducts inspections on an 18-month cycle, Western Australia on an 18-month to two-year cycle, while Victoria and South Australia follow a three-year cycle.
The requirements with regard to equipment, appliances and resources varied considerably. The use of dispensing barcode scanners was mandatory in Victoria, Tasmania and Western Australia, whereas the other jurisdictions only recommended the use of scanners.

**PHARMACISTS’ ANNUAL REGISTRATION REQUIREMENTS**

Consistent with international pharmacy trends, and in response to the Wilkinson Review recommendations and national trends in other health professions, mandatory continuous professional development programs have been developed or are being developed in most states since 2004 (Wilkinson, 2000; International Pharmaceutical Federation, 2002; Hooper, 2004a):

- The South Australian Enrich program requires registrants to complete a personal declaration of competency in their practising area and complete a specified number of continuous education credits per year;
- Victoria implemented a similar program, EnrichVic, in January 2007;
- Tasmanian and ACT pharmacists need to sign a declaration that they are competent and that they have maintained a professional portfolio, which is subject to random audit;
- Queensland is in the process of developing requirements for ongoing competence; and
- New South Wales will consider options for ongoing assurance of competence in the near future.

Current government policy in Western Australia opposes the implementation of annual re-registration requirements requiring proof of continuous professional development.

The Pharmacy Boards of Victoria, South Australia, Northern Territory and ACT issue pharmacists with annual practising certificates. The Pharmaceutical Council of Western Australia similarly issues pharmacists with a licence to practice whereas the Pharmacy Boards of New South Wales and Tasmania
issue registration cards. An online public register has to be accessed to ensure a pharmacist has current registration in Queensland.

None of the jurisdictions presently require registrants to hold a current first aid certificate.

**PRE-REGISTRATION PHARMACIST TRAINING AND REGISTRATION REQUIREMENTS**

The pre-registration requirements and programs differ considerably between states. The two territories do not offer training programs and require pre-registration pharmacists to enrol in interstate programs. Variations in the pre-registration supervised practice time period to be completed by candidates were also identified, as summarised below:

- Queensland requires a minimum of 1824 hours over at least 48 weeks. Similarly, Victoria, South Australia and Tasmania require approximately 12 months or 52 weeks, with 4 weeks’ leave included;
- New South Wales requires 2000 hours for pre-registration students who completed their tertiary education in that state, but require interstate graduates to complete 52 weeks of supervised training;
- However, to qualify for enrolment as a pre-registration pharmacist in Western Australia, students must have already completed 500 hours of supervised training in a Western Australian pharmacy (excluding university placements). Once enrolled, pre-registration pharmacists in Western Australia then need to complete another 2000 hours. Therefore, the supervised training time period required in Western Australia is 2500 hours in total, which is significantly more than the other states.

In Queensland, New South Wales and Victoria the state branches of the PSA are the training program providers. In Victoria, Monash University is also a training provider; therefore, this is the only state with two training providers. In South Australia, Tasmania and Western Australia, the registering authorities themselves provide the training programs.
All states conduct a number of assessments consisting of both written and oral components. All of the jurisdictions use the Competency Standards developed by the PSA as a frame of reference to assess the pre-registrants’ competence. As of 2007, all states require pre-registrants to pass the Australian Pharmacy Competency Assessment Test (APCAT). Of specific interest is the situation in Queensland where the Pharmacists Board of Queensland does not conduct a final assessment of the pre-registrants. The entire assessment process has been delegated to the PSA (Qld branch), and accordingly the Board has no direct control over the assessment procedures and standards for pre-registration pharmacists.

The Australian Pharmacy Examining Committee (APEC), a standing committee of the Australian Pharmacy Council, oversees the registration of overseas trained pharmacists. All overseas trained pharmacists are required to be assessed for competency to practise in Australia through a formal APEC process, which ensures national consistency in the assessment and registration of overseas trained pharmacists.

**Pharmacist and Student Registers**

All of the jurisdictions maintain registers of pharmacists. Victoria is presently the only state that registers pre-registration pharmacists. New South Wales, with the commencement of the *Pharmacy Practice Act 2006 (NSW)*, will register pre-registration pharmacists in future. The other states only keep records of pre-registration details that include the location, name of the supervisor and commencement and completion dates.

Victoria is the only state that registers pharmacy students (≥ 2nd year), and none of the jurisdictions presently register pharmacy support staff.
SUMMARY

The results highlight the diverse set of legislation under which the pharmacy registering authorities operate, and the variation between the roles of the authorities in the various jurisdictions. Different definitions apply in regard to disciplinary processes and the extent to which the registering authorities are able to sanction practitioners. The definition of what constitutes professional misconduct of a sufficiently serious nature to justify suspension also varies between jurisdictions. There are differences in the utilisation of the practice standards developed by the professional organisations, which impact directly on administration processes and the extent to which the standards are used in disciplinary processes, decisions and outcomes.

Significant differences were also identified in regard to pharmacy premises registration, the inspection of premises, and the equipment that must be kept on premises. Such differences impact directly upon practice risk management procedures. For example, as dispensing barcode scanners are mandatory only in three jurisdictions, there may be differences in dispensing processes and risk management procedures implemented by pharmacists between jurisdictions. Differences between pre-registration programs and the assessment of pre-registration pharmacists were also identified. These differences impact upon the required hours of training and the assessment of competence. Initial and ongoing registration specifications of pharmacists also differed throughout Australia, resulting in different requirements regarding proof of competence throughout the jurisdictions.
CHAPTER 5 – DISCUSSION

5.1 INTRODUCTION

The Australian/New Zealand Standards on Risk Management and Donabedian’s approach were combined as a conceptual framework to interpret the research findings. The regulatory framework formed the structure of the study and the risk management steps were used to evaluate practice processes and risk management procedures. The integration of these two approaches was successful in guiding the research and could be used in similar future research.

Pivotal to the findings are those issues that impact upon the regulation of the profession, and those issues relating to services that potentially cause risks in community pharmacy practice. This chapter covers the key findings under these headings. In addition, the appropriate utilisation of pharmacy support staff was identified as an important aspect in the development of community pharmacy risk practices and is discussed separately. This is followed by a discussion of the study limitations.

5.2 KEY FINDINGS: PHARMACY REGULATION

The analysis confirmed the regulation of the pharmacy profession in Australia is diverse and complex. It is influenced by the different approaches of the jurisdictions, as well as the co-regulation and self-regulation models that exist between the pharmacy registering authorities and the professional organisations. The model is further complicated by the differences in the authorities’ utilisation of the professional practice standards.

This section highlights the identified regulatory issues that potentially impact on risk management practices in community pharmacy, with specific reference to Queensland regulation.
HARMONISATION AND NATIONAL REGISTRATION

Despite the disparity in the legislative provisions, the pharmacy registering authorities have made some positive moves towards harmonisation and uniformity of qualifications and professional standards through the Australian Pharmacy Council. However, many of the legislative requirements still vary significantly between states and territories, and this impacts upon pharmacy practice.

Comparing the state and territory pharmacy regulatory requirements identified diversity in the regulation of the pharmacy profession throughout Australia. These differences in standards between jurisdictions may, in the medium to long term, lead to differences in individual pharmacist competence derivative of inconsistencies that apply to initial and ongoing registration and proof of continuous professional development. The inconsistencies are further complicated by the variation in the processes and procedures pharmacists are required to follow in the provision of pharmaceutical services. Significantly, such inconsistencies in the regulation of the profession can impact upon the quality of pharmaceutical services provided throughout Australia.

The comparison highlighted the various differences impacting on the regulation of pharmacists and pharmacy practice between the jurisdictions. The identification of these differences is timely, as Australia has commenced a review process of the regulatory framework for all health professionals. This has been done under the auspice of the Council of Australian Governments (COAG) that, in July 2006, agreed to establish by July 2008 (Council of Australian Governments, 2006):

- A single national registration scheme for health professionals; and
- A single national accreditation scheme for health education and training.

The single national registration scheme will be introduced to facilitate workforce mobility, improve safety and quality, and reduce red tape, while the single
national accreditation scheme will be introduced to simplify and improve the consistency of current arrangements.

These COAG recommendations have the potential to cause major reforms in the regulation of all Australian health professionals. The proposed national registration scheme will impact upon the regulation of the pharmacy profession through the introduction of a single statutory body that will, *inter alia*, register pharmacists from all states and territories. The effect of the reforms on the regulation of pharmacy will, however, only be known once implementation has occurred. Input received from a wide range of stakeholders indicated a preference for maintaining complaints and disciplinary functions at state and territory level.

The Australian Pharmacy Council has made submissions to COAG highlighting the fact that the Australian Pharmacy Council was established with pharmacy registering authorities’ support in recognising that national registration was both desirable and inevitable (Council of Pharmacy Registering Authorities, 2006b). Although the ongoing role of the Australian Pharmacy Council following the proposed reforms is unclear, it may provide an opportunity for its current powers to be broadened, thereby facilitating pharmacy regulatory consistency.

The comparison of the regulatory requirements highlighted the many differences between jurisdictions. Therefore, reform of the Australian framework for pharmacy regulation under the direction of the recent COAG initiative will be difficult. Accordingly, COAG may need to focus on simpler early reforms, such as a national pharmacy register, before addressing the complicated issues of consistency of disciplinary outcomes, pre-registration programs, and annual pharmacist registration requirements. However, harmonisation of all of these issues are important as the current inconsistencies cause risks for both pharmacists in terms of uncertainties regarding expected practice standards, as well as for patients in terms of the patients receiving varying levels of pharmaceutical services.
QUEENSLAND REGULATION

The analysis of Queensland regulation was considerably more detailed than the other jurisdictions, as the study included the analysis of Queensland disciplinary cases, and all interview participants were from Queensland. A discussion of some of the identified Queensland-specific issues follows.

A review of the Pharmacists Board of Queensland bulletins indicated that limited information was provided to registrants regarding investigations and disciplinary cases. However, transparency and consistency in the disciplinary process are important elements for registrants, as these should assist in understanding the importance of maintaining professional standards, and the potential consequences of unsatisfactory professional conduct. The disciplinary process is a tool for defining qualities expected of pharmacists that simultaneously demonstrates how simple things can sometimes go wrong – it helps to define the ‘big stick’.

Ideally, registrants should be familiar with Board processes and the evidence used in disciplinary processes. Accordingly, not providing registrants with detailed information about the types of incidents leading to investigative and disciplinary processes makes it difficult for them to know what conduct or behaviour, carried out by a pharmacist as part of their professional role, could potentially lead to disciplinary action. The analysis indicated that the educational value of the investigative and disciplinary processes is therefore not fully utilised by the Board, or other parties, to improve the standard of practice.

It has come to light that cases that simply go through investigations without proceeding to disciplinary action need to be kept confidential. However, the reporting can be done in an anonymous way.

The absence of feedback to registrants was specifically evident in the case involving the death of a patient due to a tramadol overdose. This case serves as an excellent example of the importance of providing proper dosage instructions, and highlights the potentially devastating consequences of not doing so. The case could have, and should have, been used to educate other
pharmacists to prevent similar incidents from occurring in the future. Instead, the case was not communicated to registrants, and the educational value of the dispensing error was lost.

In a number of the disciplinary cases, workload was identified as representing an unacceptable risk to the public. Unfortunately there is a lack of research-based data concerning a safe or acceptable workload. It is an extremely complex task to determine a dispensing norm per pharmacist, as various issues need to be considered. These include the complexity of the item and the involvement of dispensary assistants to perform certain tasks involved in the dispensing process. A figure of 15 prescriptions-per-pharmacist/hour was accepted by the Victorian and South Australian Pharmacy Boards as being professionally appropriate for a pharmacist. However, since that recommendation was made, many changes have occurred to dispensing practices, including a significant improvement in pharmacy dispensing systems, and the widespread use of computer-generated prescriptions. Accordingly, a need for further research into this area of pharmacy practice has been identified.

Although the Pharmacists Board of Queensland distributes Board bulletins, and these and other Board documents are available through the Board’s website, the interview analysis identified that participants overall were not familiar with the Board’s policies and guidelines. Only a few participants were familiar with the Board’s website. Therefore, the Board should explore additional ways of reaching registrants, such as e-mails, to communicate important messages. Another issue identified as needing consideration is the overlap between some of the Board’s developed policies and guidelines and the endorsed standards and guidelines, as summarised in Table 4.1. The different standards for the same services create confusion, as it is unclear which document would be overriding; and hence it is not clear which document would be used by the Board in disciplinary proceedings. This could impact on practice processes and procedures followed by registrants.
The comparison of the regulatory requirements throughout Australian jurisdictions indicated that Queensland is the only jurisdiction in which the Board does not conduct the final pre-registration assessment. Instead, in Queensland the assessment is being conducted by the PSA (Qld branch) as part of the pre-registration program. Therefore, the Board does not assume responsibility for the assessment process and the level of achievement. However, sections 12(a) & (b) of the *Pharmacists Registration Act 2001* (Qld) specify that it is a function of the Board to ‘assess applications for registrations’; and ‘to register persons who satisfy the requirements for registration’. As it is the Board’s responsibility, and not that of the PSA, to ensure that new registrants are competent, the Board must reconsider the current process.

Queensland is one of three jurisdictions that do not register pharmacy premises. It is therefore limited in the level to which it controls premises and is able to address deficiencies. The Board is one of four jurisdictions that do not conduct regular pharmacy inspections, and only inspect a pharmacy premises which is under investigation. It therefore seems that the Board’s functions are limited to being reactive, rather than proactive. In discussing the USA system, Svarstad has argued that it is not enough to enact statutes or regulations, but that concerted efforts in multiple arenas are needed to achieve widespread change (2004). However, the role of monitoring compliance with practice requirements in Queensland community pharmacy has, to a large extent, been delegated to the Guild through Quality Care Pharmacy Program (QCPP) accreditation. Nevertheless, it is only when legislation is accompanied by implementation and enforcement systems that statutes become powerful forces that can change a profession (Nichol & Michael, 1992). Accordingly, the Board should play an important role in the implementation of legislation with regard to the changed role of pharmacists.

Under section 20 of the *Health Quality and Complaints Commission Act 2006* (Qld) health providers have a duty to monitor and improve the quality of their health services. The Health Quality and Complaints Commission (HQCC) encourage the users of health services to contact the Commission about concerns or complaints about a health care service, or a health care provider.
The HQCC assist health service providers and the users of health services to resolve issues through (Queensland Health Quality and Complaints Commission, 2007):

- The assessment of complaints and investigating how it may be resolved;
- Seeking comments and medical records form the health service provider or an opinion from another clinician; and
- A conciliation process that is done in a privileged environment

Those complaints that do not result in a resolution may be referred to the health professional’s relevant registration board. The role of the HQCC is therefore *inter alia* to provide a supportive environment in which consumers can have their questions or concerns addressed and to assist health service providers to develop procedures to effectively resolve complaints (Queensland Health Quality and Complaints Commission, 2007). Through the HQCC and in terms of section 28L of the *Health Services Act 1991* (Qld), regional Health Community Councils have been established during July 2007. Section 28M of the Act outlines the functions of these Councils, namely to focus on:

- Quality and safety of public health services;
- Community and consumer engagement; and
- Community education in relation to the public health system.

These Councils serve as advisory bodies across Queensland to play a key role in the governance of public health services. The Councils would therefore play an important role in the improvement of the quality of health services within the public sector. However, a similar focus needs to be placed on the provision of health services within the private sector.

The above discussion highlights regulatory issues impacting on community pharmacy in Queensland, and the differences between Queensland regulation and the other jurisdictions. The analysis indicated that these issues need to be
considered by regulators and policymakers to ensure best patient outcomes, as well as improving consistency with other jurisdictions.

**DISCIPLINARY PROCESSES AND OUTCOMES**

The disciplinary process followed by the Pharmacists Board of Queensland overall seemed just and complied with the principles of natural justice. However, there was some inconsistency in the way the Board used endorsed practice standards and guidelines as a frame of reference.

Disciplinary sanctions imposed on registrants should not follow a punitive approach, but should instead seek to protect the public by specific and general deterrence (Freckelton, 2004). On the other hand, an important function of professional disciplinary mechanisms is the publicity given to breaches (Tito, 1994), which thereby deter other pharmacists from similar behaviour. These two opposing outcomes that need to be achieved must be carefully considered, and complicate the disciplinary process. These different outcomes could have played a role in the two analysed disciplinary cases that demonstrated a deviation from the sanctions imposed in previous cases with similar facts.

The difficulty in weighing the interests of practitioners against the interests of the public was also demonstrated by two Pharmacy Board of Victoria disciplinary cases. The outcomes of these two cases were appealed, and the Supreme Court of Victoria subsequently did not support the penalties imposed by the Board, but instead imposed less severe penalties: In *Mercer v Pharmacy Board of Victoria* [1968] VR 72, the court upheld the Pharmacy Board of Victoria’s finding that a pharmacist had been guilty of conduct discreditable to a pharmaceutical chemist. In this case the pharmacist was absent from his pharmacy while it was open. This behaviour occurred despite undertakings by the pharmacist to the Board in 1963 that he would fully observe the responsibilities of a pharmacist, with special regard to qualified supervision and observance of the sale, custody and recording of medicines. Pape J made the following comment in considering the Board’s penalty of cancellation of registration [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.

Still, the court found the penalty imposed by the Board was too severe, and imposed a less severe sanction, namely a four-week suspension. In the case of *Ha v Pharmacy Board of Victoria* (2002) VAR 322, Gillard J considered the consequences of suspension of a pharmacist's registration, and concluded that in this case, suspension was not necessarily to protect the public, but rather to maintain the profession's standing. He held that where the issues before the court [at 84]:

... 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 on the penalty.

Although the court upheld the Board's finding of professional misconduct, it found the three months' suspension unreasonable considering the circumstances, and imposed less severe penalties. Mr Ha was fined $1,500 and given a two-year community-based order to perform unpaid community work, and to undergo psychological or psychiatric treatment as directed.

Part of the disciplinary process is to maintain appropriate standards within the profession, and as stated above, to maintain public confidence in health professionals. Therefore, the question is whether the courts' lighter sanctions in these two cases were in the best interest of the public, as well as in deterring other pharmacists from similar actions?

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. It is, nonetheless, important that pharmacists are informed of disciplinary outcomes to enable them to predict the consequences of unprofessional conduct. However, the
poor utilisation of the educational value of disciplinary cases is not specific to Queensland, and New South Wales is the only jurisdiction that publishes all disciplinary case outcomes. All other jurisdictions publish only the more serious outcomes.

The New South Wales system is similar to that in the UK, where all of the RPSGB Statutory Committee’s decisions are published in the Society’s official journal, the *Pharmaceutical Journal*. An analysis of UK disciplinary cases indeed indicated that, over a 12-year period, the nature of conduct leading to disciplinary cases changed little (Tullett *et al.*, 2003), despite changing roles and risks. The researchers concluded that the publication of cases serves to deter other pharmacists from similar conduct. It is also playing a role in keeping the number of persistent offenders low: ‘Indeed, publication of each case in detail in the *Pharmaceutical Journal* may have played a part in this’ (Tullett *et al.*, 2003 p. 50). Disciplinary outcomes should therefore be used as a tool to improve practice, and better communication of cases should be promoted to pharmacy registering authorities.

The disciplining of practitioners who do not comply with acceptable standards of care or behaviour is a major role of pharmacy registering authorities. It is important that disciplinary processes and outcomes be consistent across jurisdictions, especially with the introduction of national registration – an issue needing consideration by the pharmacy registering authorities through the Australian Pharmacy Council.

**PRACTICE STANDARDS AND GUIDELINES**

Professional practice standards and guidelines form an integral part of the regulation of the profession as they form a frame of reference of good practice and are used in disciplinary decisions.

Two principles were considered in the analysis of the utilisation of the practice standards, namely that following good practice standards firstly is a means to provide good patient care, and secondly assists with risk management.
Therefore, implementing the standards addresses the development of systems to help prevent errors occurring. As the pharmacist’s role has changed significantly and pharmacists now accept a more involved role in patients’ medication management, it is particularly important that pharmacists follow good standards to protect them against potential litigation.

The interview analysis aimed to provide insight into the extent to which pharmacists incorporate practice standards into everyday practice to identify and manage risk. The analysis identified that practising pharmacists were not familiar with the detailed criteria of the Professional Practice Standards, and did not grasp the risk management value in implementing the standards. In contrast, all of the participants were familiar with the S2/S3 Standards. The familiarity with the S2/S3 Standards is a reflection of the Guild’s emphasis on the S2/S3 Standards as part of the ongoing evaluation of the need for two separate OTC Schedules by the National Co-ordinating Committee on Therapeutic Goods (NCCTG).

The comparison of the regulatory requirements of the various pharmacy registering authorities indicated there are differences with regard to the extent to which the authorities use the practice standards: (1) in the administration of their functions; (2) in the determination of the required standard of practice; and (3) as admissible evidence in disciplinary proceedings. These regulatory differences potentially impact upon community pharmacy practice, and the risk management procedures developed and implemented by pharmacists throughout Australia.

The analysis of the Pharmacists Board of Queensland disciplinary cases indicated that all of the errors occurred because the pharmacists did not follow the applicable standards or guidelines. The analysis also indicated a degree of inconsistency in the way the Board used the standards and guidelines as admissible evidence. The inconsistency could have been due to changes in the investigative processes and staff members involved in the investigations; these changes took place during the period of analysis.
Another explanation for the inconsistent use of the standards in the disciplinary process is the large number of standards and guidelines that have been endorsed by the Board, therefore: (1) making it difficult to decide which one to refer to in disciplinary cases; and (2) making disciplinary decisions less predictable for pharmacists, as it is not clear which of these would be the overriding document. Considerable overlap exists between several of the endorsed standards and the policies and guidelines developed by the Board. It is not clear which document would be used by the Board as a frame of reference in disciplinary proceedings.

In a March 2007 communication to registered pharmacists in Queensland, the Pharmacists Board of Queensland highlighted certain amendments to the *Health (Drugs and Poisons) Regulation 1996* (Qld) made during 2006. These amendments relate to the need for quality standards in the dispensing and selling of scheduled medicines (Pharmacists Board of Queensland, 2007a). It stated that a quality standard must be consistent with the following principles (p. 1):

- In selecting a way to manage a person’s condition, a pharmacist should consider appropriate options, including, for example, medicinal and non-medicinal options;
- For a medicinal option, the pharmacist should choose the medicine the pharmacist considers is the most appropriate having regard to relevant matters, including, for example, potential risks and benefits of using the medicine; and
- A medicine should be used in a way that:
  - maximises the efficacy of the medicine; and
  - minimises misuse of the medicine.

Additionally, these legislative amendments require that pharmacists follow those standards recognised by the Board. As the Board has endorsed all of the practice standards developed by the PSA and the SHPA, there is a requirement in terms of the Regulation to follow these standards. With these amendments the Regulation has moved away from the previous ‘narrow’ definitions of dispensing and the supplying of S2 and S3 medicines to those definitions and criteria developed and recognised by the professional organisations. These amendments were made in recognition of the changed role of pharmacists and practice developments. Hence, the standards applicable to the dispensing of
prescribed medicines and the selling of S2 and S3 medicines would, in future, be relied upon more heavily as evidence of required practice in disciplinary proceedings (Hattingh et al., 2007b).

From an organisational perspective, the pharmacy professional organisations have accepted a major role in developing practice standards and processes for use by community pharmacists. Although these standards are not developed from a legal basis, they are used in disciplinary cases by the pharmacy registering authorities. To complicate things further, the standards do not distinguish between the ‘must-do’ functions and the ‘nice-to-do’ functions – the minimum requirements versus the aspirational.

The analysis indicated that the implementation of the standards by pharmacists would improve if the standards focused on the crucial aspects to ensure safe patient care. The detail should therefore be removed for incorporation into the practice guidelines, which should include step-wise descriptions of certain tasks that are process-focused. This will assist pharmacists with the development of workflow models. For example, the technical steps involved in the dispensing process such as data entry, medication selection and the labelling tasks should be described in guideline steps. This would make it easier to design workflow and to delegate these functions to appropriately trained support staff.

The analysis indicated a need to simplify the standards, and for it to be designed in such a way that a clear differentiation exists between the purposes of the standards and the guidelines. The guidelines, as such, should therefore be designed as supplements to the standards, and be used as tools to help implement the appropriate standard of practice. Step-wise processes should be included in the guidelines where appropriate.

As the standards and guidelines are used in disciplinary decisions, it would seem logical for the pharmacy registering authorities to be more involved in the development of the standards. This involvement could be driven by the Australian Pharmacy Council, and would not only promote uniformity across
jurisdictions, but would also better support the purpose of the standards, namely that they are developed with the ultimate goal of ensuring safe patient care.

**SELF REGULATION**

The Quality Care Pharmacy Program (QCPP) has been an important self-regulation vehicle for driving and implementing change management within community pharmacy. It is the tool through which the Guild has facilitated the improvement of quality services within community pharmacy. Pharmaceutical Defence Limited (PDL) has also supported the QCPP, and has stated that a court would probably consider a pharmacy’s accreditation status in the case of an error (Pharmaceutical Defence Limited, 2006).

QCPP is directed at enabling community pharmacists to benchmark them against a best practice model. Although the initial program focused on business operation within a retail environment, the PSA Professional Practice Standards and S2/S3 Standards have now been incorporated into the program. Therefore, it has developed from the initial business management program to also include professional standards. The introduction of the professional component has played an important role in the marketing and implementation of the standards: under the QCPP, pharmacy owners need to show proof of their pharmacies’ compliance with the standards applicable to the pharmacy, depending on the types of services offered. Additionally, employee pharmacists need to sign an annual declaration regarding compliance with the standards (Pharmacy Guild of Australia, 2006b).

The initial intention was that only those pharmacies with QCPP accreditation would be eligible to receive certain financial rewards for certain services, administered by Medicare Australia, for example providing Home Medicine Reviews. However, the Medicare Australia rules have not changed, and pharmacies that are not accredited are therefore not excluded from receiving payment for providing these services. The financial incentive to undergo accreditation has therefore not been enforced, and as accreditation is claimed to be complicated and very time-consuming, banner groups are starting to
develop their own accreditation packages. It may therefore be that a variety of community pharmacy accreditation programs will exist in the future, which may impact on consistency of practice standards and processes.

Under the QCPP, pharmacies are required to undergo an external audit every two years in order to remain accredited. These audits are conducted by QCPP-licensed assessors, who are trained professionals with a detailed background in pharmacy practice. Therefore, the Guild is the standard-setting body, as well as the accrediting body. A shortcoming of the audits is that they do not include the observation of staff to ensure they follow standard operating procedures. Accordingly, although the program has been implemented since 1998, evidence about exactly how, and by what means, pharmacists utilise the standards is still lacking, as this is not covered in detail during the audits. Another shortcoming is that the marketing of the program focuses on its uptake, and not on areas in which pharmacies need to improve. Although a bulletin is regularly sent to participating pharmacies, there is no quality feedback regarding compliance and non-compliance with the professional standards. Hence, feedback to pharmacists has only limited educational value.

The interview analysis indicated that many of the pharmacists do not integrate the QCPP professional components into their everyday practices, but rather tend to comply with the requirements only when going through accreditation or re-accreditation. Therefore, although it is a requirement under the QCPP that pharmacists sign an annual declaration of compliance with the applicable standards, the interview analysis indicates that many pharmacists do not yet fully integrate the standards into their daily practices.

The QCPP is a tool available to community pharmacists for standardising the provision of pharmaceutical services. As stated by the Guild (2006b) in a response to *The Commission on Safety and Quality in Health Care Discussion Paper – National Safety and Quality Accreditation Standards November 2006*, it has been developed by community pharmacy, for community pharmacy. Therefore, to some extent, the Guild dictates the standard of community pharmacy practice through the program. However, the comparison of the
regulatory requirements imposed by the various pharmacy registering authorities indicated that the various jurisdictions assign different values to the QCPP; namely that some jurisdictions endorse the program, while others recognise it, and others support it. This inconsistency potentially causes differences throughout the jurisdictions with regard to the provision of services, as QCPP accreditation is not mandatory.

Although the program has been shown to be an effective tool in driving the improvement of quality community pharmacy services, the role of quality improvement should not solely be the profession’s responsibility. Standards implementation should be driven by both the profession and the pharmacy registering authorities.

**SUMMARY**

The regulation of the profession must be reviewed on a continuous basis not only to reflect the changes in practice, but also to assist in driving these changes. However, the analysis indicated that the regulatory approaches needs to be reviewed to ensure implementation of changed practice requirements, and to improve consistency across jurisdictions. Current risk areas in everyday practice need to be considered in regulatory improvements, as these should influence reform.

**5.3 KEY FINDINGS: PRACTICE RISK MANAGEMENT**

An integral part of risk management is the analysis of the potential for risk and then designing the systems and processes that address and alleviate potential negative outcomes.

The analysis of the disciplinary cases provided a wealth of information regarding practice risks and those situations in which pharmacists did not manage the risks, which in many of the instances caused a negative patient outcome. The cases not only provided information on the types of errors
leading to disciplinary action, but also on the way in which the Board utilised practice standards and resources to determine what should have been the appropriate standard of care. On the other hand, the interview analysis provided in-depth information regarding pharmacists' knowledge of practice risks and their reaction to and management of identified risks. It gave an in-depth understanding of contemporary practice, and highlighted the areas that should be addressed to reduce pharmacists' risk.

The following is a discussion of contemporary community pharmacy risk areas identified through the analysis.

**Pharmacists’ Advisory Role**

The changed role of community pharmacists requires them to allocate more time in order to communicate health-related and medication-related information to patients. The advice and information provided by pharmacists can broadly be divided into two categories, namely:

- The advice given to manage minor ailments, with or without the supply of non-prescription/OTC medicines; and
- The advice provided with the dispensing of prescription medicines.

**The management of minor ailments:**

In defining the role of the pharmacist, the World Health Organisation (WHO) has indicated that community pharmacists should play a major role in the management of minor, self-limiting conditions through the supply of OTC medicines and the advice about the management of these conditions (World Health Organisation, 1997). However, the interview analysis indicated:

- A huge variation exists in the quality of services provided by community pharmacists with regard to the supply of OTC therapies. These findings support the Mystery Shopper Program results that demonstrated that there are a significant number of pharmacists who
are not complying with the behavioural and counselling requirements of the S2/S3 Standards. In line with the interview analysis, the Mystery Shopper Program results indicated considerable disparity in the level of advice delivered, and found that in some cases when S3 medicines were supplied, no advice was offered at all (National Co-ordinating Committee on Therapeutic Goods, 2005).

- Most pharmacists provide limited evidence-based training for support staff regarding OTC medicines, instead relying heavily on pharmaceutical companies to provide product information. While the content of materials from pharmaceutical manufacturers was not evaluated as part of this study, it is well known that this is often promotional in nature, and does not have an evidence-based focus.

- Many pharmacists mainly stay in the dispensary, leaving it to ‘front shop’ staff to assess the need, judge the appropriateness and recommend the supply of OTC medicines.

- OTC supply procedures were mainly focused on the implementation and development of processes covering the supply of S3 medicines only in order to comply with the recording and other legislative specifications in Queensland.

The analysis of the disciplinary cases reinforced pharmacists’ legal liability when supplying S3 medicines. Of specific interest is the case that involved the supply of Xenical® to a 15-year old, in which the pharmacist failed to determine a therapeutic need and to provide advice to the patient. Additionally, it was a supply to a 15-year old, which constitutes a breach of the Queensland legislative requirements. The fact that in this case the breach was considered serious enough to follow through the investigative process to disciplinary action demonstrates the significance that the Board attaches to the responsibility given to pharmacists in the supply of S3 medicines.
In the UK, research has been conducted into the development of a tool for pharmacists’ evaluation of the management of minor ailments (Ward et al., 2000). The criteria focused on the content of advice, rational product choice, and referral to another health professional. Similarly, researchers in Finland developed a patient counselling-specific quality assurance instrument to measure the advice provided by pharmacy staff. However, no similar research nor tools have been conducted and developed in Australia.

Advice with dispensed medicines:

With regard to the giving of advice with prescription medicines, the interview analysis indicated:

- Most pharmacists do not provide advice on dispensed medicines in a consistent way. Of the 17 community pharmacists interviewed, only four indicated that it was the pharmacy’s policy to reserve this advisory role for pharmacists. However, the Pharmacists Board of Queensland Guidelines regarding the use of dispensary assistants specify that this function should be performed by pharmacists, and not by pharmacy support staff. As the policy uses the term ‘should’ and not ‘must’, it is not totally clear and leaves it to pharmacists to decide under which circumstances they can delegate this function to support staff. This issue therefore requires clarification.

- Counselling tools such as CMI leaflets and pharmacy self care cards are often passively provided instead of being used proactively to support the cognitive role of the pharmacist. This finding is similar to comments made by Goodman (2006a).

The analysis of the disciplinary cases demonstrated that the majority of the cases that involved a dispensing error could have been avoided had the pharmacist provided the required advice. Therefore, in addition to the fact that counselling improves the QUM, it also provides pharmacists with the opportunity to finally check the product that is being handed out. Hence,
counselling is an important risk management strategy, and pharmacists who do not routinely counsel patients increase their dispensing error risk.

The provision of appropriate advice is an important medication management role of pharmacists – one that not only requires clinical knowledge, but also communication skills. It requires that pharmacists use professional judgement to interpret the information in the context of a specific patient's other medication and co-morbidities. Advice should not only encompass therapeutic issues but also lifestyle issues, when appropriate. Contemporary university curricula include the training of pharmacy students in determining which counselling points are most relevant in a specific situation. These skills are assessed through dispensing and counselling examinations. Support staff, on the other hand, do not have the academic background to provide patients with the most relevant advice and to tailor it to the individual patient’s needs. Disappointingly, most of the interviewed pharmacists relied on support staff to perform this function, particularly for patients with repeat prescriptions.

The analysis showed that criteria and tools need to be developed to assess the standards and quality of advice provided in Australian community pharmacies. This will assist the profession in proving the value of pharmacists’ advice, and in targeting specific areas that need improvement.

**Patient versus product focus**

The analysis indicated that processes and protocols involved in the supply of OTC products mainly focused on the scheduling status of the products, rather than on patients.

The majority of interview participants had very few processes in place with regard to the supply of S2 medicines, and S2 medicine supplies had limited pharmacist involvement. However, five of the 17 participants indicated that their staff were also being trained to ask specific questions when certain OTC medicines were involved, in order to ensure patient safety. This approach, namely to ask relevant questions to determine the appropriateness of the
product when supplying OTC medicines other than S3 medicines, is in line with the comments that were made in 2001 by Galbally through the Review of Drugs, Poisons and Controlled Substances Legislation (2001, pp. xii-xiii):

Given the wide and increasing range of OTC medicines and the potential for harm, appropriate counselling and advice has the potential to prevent some significant hospital and medical costs which could result from inappropriate selection and use of medicines or drug interactions. However, despite a number of standards on the way in which counselling should be delivered, there appears to be considerable disparity in the level of counselling delivered. Further, such counselling is often initiated by the consumer which could lead one to conclude that there is no need to mandate that supply only be permitted where that counselling is available.

...the restrictions on access are intended to complement requirements of the Pharmacy Acts to provide a mechanism to redress consumers’ information and understanding deficit in relation to OTC medicines. However, counselling doesn’t always occur when it ‘should’. This is in part because counselling is mandated to occur when the risk may be low. This dilutes the effectiveness and so it becomes cost-ineffective and possibly ineffective altogether.

A risk-based code of practice ... could ensure more effective counselling is provided when necessary across all Pharmacist Only (S3) or Pharmacy Medicines (S2) sales, not because they are Pharmacy Medicines (S2) or Pharmacist Only (S3) Medicines but because, for that consumer, the risk-based triggers were activated. (p 37)

Therefore, Galbally identified that the quality of pharmacists’ involvement in the supply of S2 and S3 medicines is determined by the scheduling arrangements, and not by the risks involved with individual patients or the care that a specific patient requires. Although the S2/S3 Standards were revised to incorporate Galbally’s recommendations, the interview analysis indicated that very few pharmacists have indeed implemented a risk-based, patient focused approach in the supply of OTC medicines.

Similarly, the National Co-ordinating Committee on Therapeutic Goods (NCCTG) reported to the Health Ministers that the extent of professional intervention benefiting the community at present is dependent on a medication’s scheduling status (National Co-ordinating Committee on Therapeutic Goods, 2005) and not necessarily on patient risk. It was further noted that a particular schedule in which a medicine has been placed will not always be a good predictor of the potential harm it may cause if used inappropriately. Instead, the
NCCTG recommended that critical factors such as underlying health conditions, other medications used, and how the medicine is being used, need to be considered. The report noted that the triggers that should elicit pharmacist intervention should indeed focus more on the patient than on the specific medication. The NCCTG is therefore currently re-evaluating the need for two OTC schedules, and will make a final decision in 2010.

It has been suggested that part of the problem lies in the terminology used, and that the term ‘Over-The-Counter’ is not appropriate, as it leads to everyone aligning them with normal items of commerce (Goodman, 2006a). Accordingly, it may be more appropriate for these medicines to instead be classified as ‘prescribed by pharmacists’.

The legislative requirements regarding S3 medicine supplies require that pharmacists be involved in the decision-making process as to whether S3 medicines should be supplied, and also to provide patients with advice regarding the appropriate use. However, most of the interview participants indicated that while they were often not directly involved in the supply, they complied with the legislation through artificial ‘check-box’ approaches: the support staff would obtain the information from the patient, provide the information to the pharmacist, and the pharmacist would then ‘approve’ the supply without personally talking to the patient. It therefore seemed that many pharmacists’ approach is focused on doing the minimum to comply with the legislative requirements, instead of providing good patient care. These findings are similar to previous surveys done by the Australian Consumers’ Association (ACA) and cause reason of concern as high or medium risk patients (e.g. patients on multiple medications or the elderly) may be exposed to medication misadventure.

The analysis indicated that many pharmacists need to change their practice protocols and practices with regard to OTC medication supplies. They need a paradigm shift away from merely complying with legislative requirements to one that focuses on patients’ needs for all OTC medication supplies. Risk-based approaches need to be implemented that will give rise to determining a
therapeutic need and appropriateness and provide counselling when patient factors warrant it, regardless of the medication’s schedule. Patient safety factors should play an important role in the supply of S2/S3 medicines.

Pharmacists that do not comply with the requirements are exposed to potential legal liability should a patient suffer as a result of taking inappropriate medication. However, failure to comply with the requirements not only has legal implications for the individual pharmacist, but also for the profession as a whole. Accordingly, the profession should, on an ongoing basis, demonstrate the benefit of pharmacists’ intervention. If not, pharmacists might lose the privilege of having S2 and S3 medicines available to the public exclusively from pharmacies. Additionally, the removal of the current S2 and S3 restrictions will allow these medicines to be sold by supermarkets, which will place patients at risk as there will not be any potential for intervention from a health professional.

THE DISPENSING PROCESS

Over recent years the dispensing process has developed to involve a range of steps that need to be followed to provide safe patient outcomes. However, the interview analysis indicated a lack of consistent procedures followed by pharmacists. The utilisation of dispensary assistants also varied considerably between participants, specifically with regard to workflow and the allocation of tasks. This outcome supports the literature, and indicates that dispensing errors form a major risk in community pharmacy practice.

Research has proven that the dispensing error risk is reduced by using barcode scanners during dispensing (Poon et al., 2006; Guild Insurance/Guildwatch, 2006). However, as the use of scanners is not mandatory in Queensland, many of the interview participants did not use scanners. The analysis has also indicated that, although most of the participants had basic processes in place to reduce picking errors, more strategies need to be implemented to improve the quality of dispensing services. As already discussed, one area requiring improvement is the release of pharmacists to provide patient advice, although the analysis indicated that this could be challenging in pharmacies with only one
pharmacist on duty. However, pharmacists working in pharmacies with more than one pharmacist at a time need to design the dispensing process to release at least one pharmacist to perform patient care services. This design was successfully implemented by one of the interview pharmacists: the dedicated counselling pharmacist at this pharmacy provided an additional risk management step as this pharmacist checked the dispensed medication at the time of handing it to the patient, thereby reducing errors and improving patient safety.

There are many opportunities for errors during the dispensing process. In fact, the majority of the disciplinary cases (47.7%) were caused by dispensing errors. The disciplinary case analysis showed that most of the pharmacies involved in these cases did not have adequate risk management processes in place. The risks involved with dispensing were further demonstrated by the fact that 83 of the 85 incidents reported to Pharmaceutical Defence Limited (Qld branch) were caused by dispensing errors.

Dispensing errors can have devastating consequences. Indeed, dispensing cases included two situations where errors resulted to death and three that resulted in hospitalisation. Therefore, it is important to determine why errors are occurring in order to develop systems to reduce the errors risks. The Pharmacy Board of Victoria survey identified reasons contributing towards dispensing errors as: workload, distractions and interruptions, and inadequacy of counselling (Newgreen et al., 2005). A 1998 Texas survey indicated that job satisfaction variables, prescription volume, practice site, staffing, training, pharmacist functions, and professional organisation membership strongly influenced the risk of dispensing errors (Bond & Raehl, 2001). The survey also indicated that of the 2437 pharmacists who responded, 793 (34%) reported that at least one patient per week was at risk of a dispensing error.

The analysis indicated that pharmacists are mainly involved with technical dispensing tasks, and therefore are not available to provide patient care services. However, the releasing of pharmacists to provide patient advice is complicated by the legal requirement that all dispensed products must be
checked and signed off by a pharmacist. Therefore, there are many issues involved that contribute to the complexity of dispensing and the difficulties experienced in changing practice processes. The practical challenges facing pharmacists in regard to the dual dispensing role was already identified by Strand in 1998, pointing out that ‘Pharmacists could not dispense drugs and take care of patients at the same time.’ (p. 875). One alternative is for community pharmacists to develop workflow models similar to those of hospital pharmacy; models which make better use of dispensary assistants to release pharmacists to provide appropriate patient care. The analysis indicated that there is a need for pharmacists to redesign practice processes and the delegation of functions. This needs to be done with regulatory authorities as the dispensing legislative requirements require revision.

Some discrepancy exists in the Health (Drugs and Poisons) Regulation 1996 (Qld) in relation to what exactly the dispensing function entails: dispensing is defined ‘narrowly’ in the definitions appendix as ‘selling on prescription’. However, the 2006 amendment to the Regulation introduced another definition of dispensing in sub-section 4A(c), requiring that pharmacists follow the dispensing practice standards. This amendment to the Regulation potentially has legal implications for pharmacists in terms of complying with dispensing requirements as the Board’s endorsed standards provide detailed criteria that need to be followed during dispensing. The criteria are considerably more focused on the cognitive actions involved with dispensing than the ‘narrow’ definition, thereby placing increased responsibility on pharmacists.

Additionally, generic dispensing and substitution places considerable time constraints on pharmacists as they should discuss the substitution with patients to reduce confusion and manage compliance issues. The increased legal risks involved with the growth in generic substitution were demonstrated by the one disciplinary case involving the dispensing of the incorrect product. However, the patient thought the dispensed medication was a generic substitute, and therefore used the medicine.
Part of the dispensing process includes the clinical evaluation of the prescription. The dispensing standards require that pharmacists aim to obtain sufficient information from the patient, carer, and/or prescriber to promote rational prescribing. That is, pharmacists should act as a safeguard for the prescriber – a ‘double check’ to minimise adverse events. However, Australian medical defence organisations claim that prescribing errors are on the rise, which places doubt as to pharmacists’ involvement in identifying irrational prescribing (Ferguson, 2006):

1. The Medical Defence Association of Victoria reported that prescribing errors presently make a significantly greater proportion of reported incidents than 10 years ago.

2. Similarly, United Medical Protection indicated that prescribing errors represented the third-largest group of claims against GPs with just under 13% of claims dealt with in the five years to June 2004 being based on prescribing errors.

The 2004 *Threats to Australian patient safety in general practice report* indicated that about 30% of general practice errors were prescribing errors (Statistical Clearing House, 2004). This figure is higher than the incident rates recorded by United, probably because many errors did not result in litigation, as relatively few had serious outcomes. The expanding of limited prescribing to other health professionals (e.g. optometrists and nurse practitioners) will further increase the prescribing error risk.

Pharmacists should act as a backup for prescribers in helping to identify and resolve prescribing errors, thereby preventing the errors leading to adverse events. However, the high incidence of prescribing errors and litigation involving prescribing errors indicate that many pharmacists do not sufficiently fulfil the role of clinically evaluating prescriptions.
LEGAL LIABILITY FOR DISPENSING ERRORS

Pharmacists' responsibility and legal duty to ensure the safe dispensing of prescription medicines has been laid down by the many disciplinary cases involving dispensing errors. The disciplinary approach was supported by the Supreme Court of Tasmania in the case of Adamson v the Pharmacy Board of Tasmania [2004] TASSC 32. In this case the pharmacist, Mr Adamson, incorrectly dispensed 25mg Panafcortelone® tablets when 5mg had been prescribed, and thereafter incorrectly dispensed a repeat supply of these tablets. The Court upheld the Board's decision that Mr Adamson was guilty of professional misconduct, and that his conduct fell short of the standard of a pharmacist. Therefore Mr Adamson, who had already reached the age of 80 years, had to undertake selling his pharmacy within a reasonable time and only work under supervision until it was sold.

Various overseas negligence cases similarly demonstrate pharmacists' legal liability during dispensing. The cases indicate that pharmacists not only have a responsibility to ensure they dispense what has been prescribed, but also to ensure that what has been prescribed is appropriate for the patient in terms of the choice of medicine, the dose and the usage instructions.

Correct medicine:

The UK case of Prendergast v Sam & Dee Ltd (1989) 1 MLR 36 demonstrates pharmacists' responsibility to correctly dispense what has been prescribed and to contact the prescriber if in doubt. In this case the pharmacist, Mr Kozary, misread Dr Miller's writing on a prescription for Mr Prendergast on 17 December 1983. Dr Miller had prescribed an antibiotic Amoxil® (amoxicillin) but the pharmacist had read it as Daonil® (glibenclamide), which is used to reduce blood sugar levels. On the evening of 19 December 1983, Mr Prendergast was found unconscious at home. On admission to hospital, he was found to have suffered severe hypoglycaemia. The shortage of oxygen in his blood resulted in permanent damage to his brain. In the High Court, Lord Justice Dillon held that the word 'Amoxil' as written on the prescription could reasonably have read
incorrectly. However, various aspects of the prescription should have put the pharmacist on notice that something was wrong. The Court of Appeal noted that:

- It was well established practice that if a pharmacist was in doubt he/she should contact the prescriber;
- The strength prescribed was appropriate for Amoxil® but not for Daonil®;
- The prescription was for Amoxil® to be taken three times a day, Daonil® was usually only taken once a day;
- The prescription was for only 21 capsules three times a day, which was a very short course appropriate for Amoxil® but unlikely for Daonil®; and
- Ventolin® and Phyllocontin® were prescribed with the Amoxil®. Both were well known treatments for asthma.

Taking the facts into consideration, the Court held that the chain of causation between Dr Miller’s bad handwriting and the damage was not broken. The Court of Appeal apportioned 75% of the responsibility for the patient’s injury to Mr Kozary and 25% to Dr Miller.

The 1971 USA wrongful birth case of Troppi v Scarf (1971) 187 Mich Ct App 511 is another example of the court’s approach towards assigning pharmacists the responsibility to correctly fill prescriptions. In this case, the Michigan Court of Appeals held that the pharmacist had an absolute duty to dispense the correct medicine and was liable for the ‘harm’ of an unexpected pregnancy resulting from dispensing the wrong medicine. The courts also recognised that pharmacists may have a duty to verify, or refuse to fill, a prescription that contains a patent or obvious error. Another example is the 1991 case of Nichols v Central Merchandise Inc. (1991) 817 Kan Ct App 1131, in which a Kansas appellate court stated that a pharmacist had a duty not only to fill prescriptions accurately, but also to be alert for clear errors or mistakes on the face of a prescription.

**Appropriate medicine:**

The UK case of Collins v Hertfordshire County Council [1947] 1 KB 633 indicates pharmacists’ responsibility to ensure the choice of dispensed medicine is appropriate. In this case, a patient died while undergoing an operation due to a cocaine overdose; the operating surgeon had ordered procaine over the
telephone, but the resident house surgeon misheard and prescribed cocaine. The pharmacist subsequently made up the cocaine with adrenaline mixture, which was described by Hilbery J, the trial judge, as a dosage and mixture that ‘… nobody has ever heard of injecting …. into anybody.’ The facts indicated that the pharmacist was without doubt aware that the solution was for injection. It was also shown that the hospital’s standing procedures relating to orders for dangerous drugs had been totally ignored by both the resident house surgeon and the pharmacist. The court held that both the resident house surgeon and the hospital pharmacist had contributed to the danger and the negligence. The hospital was held liable to pay the compensation to the deceased patient’s wife under the doctrine of vicarious liability.

**Appropriate dose:**

The UK High Court case of *Horton v Lloyds Pharmacy Ltd* (2006) indicates the responsibility on pharmacists to ensure the dispensed dose is appropriate for the patient. In this case the plaintiff, a USA lawyer, Cathy Horton, had an incorrect prescription prescribed by a UK doctor in July 2001, and the pharmacist at Lloydspharmacy dispensed the prescription without questioning the dose. The prescription was for dexamethasone 4mg daily instead of her maintenance dose of 0.5mg daily – eight times the dose that she had taken for a number of years. On her return to the USA, a doctor continued to prescribe 4mg 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 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 Lloydspharmacy. 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 4mg daily dose. Ms Horton claimed £5m in damages.

The apportioned liability of a pharmacist in dispensing was also demonstrated by an unreported UK case that was settled by the High Court (Appelby & Wingfield, 2005). The claim arose from a negligently written prescription for Epilim® (sodium valproate) 500mg tablets in November 1999. The strength and dosage instructions were incorrect on both the prescription and the label. The pharmacy’s professional indemnity insurer agreed to pay 25% of the settlement for the pharmacist’s failure to detect and correct the error while the prescribing doctor was held liable for the remaining 75% of the compensation.

These cases clearly indicate the responsibility and potential legal liability on pharmacists during dispensing, and can be used to explain potential risks to Australian community pharmacists. However, pharmacists’ dispensing responsibility extends beyond ensuring the appropriate medicine is chosen in the correct dose, to also providing medicine advice appropriate to the specific patient. Still, the interview analysis indicated that many pharmacists do not personally provide advice to patients about dispensed medicine, but mostly delegate this role to support staff. This practice is a risk to pharmacists and places patients in danger as patients often do not have the knowledge to ensure appropriate usage.

Pharmacists’ legal responsibility to provide patients with appropriate advice regarding the use of their prescription medicines has been highlighted by various international court decisions. These cases indicate that pharmacists must: give proper dosage instructions and indicate maximum doses to patients; warn patients of adverse effects that require medical attention; warn patients about the potential for the development of addiction to the prescribed medicine; and highlight potential contraindications.
Maximum dose:

The UK case of *Dwyer v Roderick* (1983) 127 SJ 805 demonstrates pharmacists’ responsibility to provide dosage instructions. In this case, Mrs Dwyer complained of severe headaches to Dr Roderick, who wrote her a prescription for Migril® (ergotamine tartrate) tablets, but did not prescribe the medication in proper doses. The prescription was dispensed by one of two qualified pharmacists at Cross Chemists (Banbury) Ltd. The pharmacist did not add a warning relating to maximum dosage, nor advise Mrs Dwyer that no more than four tablets should be taken for any one migraine attack, and no more than 12 tablets should be taken in the course of a week. Over the next six days Mrs Dwyer took 36 Migril tablets, which resulted in ergotamine poisoning, gangrene and the necessity to amputate some of her toes. As a result she became permanently crippled. In the High Court, both Dr Rodrick and the pharmacist admitted negligence but argued the apportionment of liability. Liability was proportioned at 55% by the pharmacist and 45% by Dr Rodrick. As a result of this case the Royal Pharmaceutical Society of Great Britain issued the following Council Statement (Merrils & Fisher, 2006, p. 270):

> Pharmacists are reminded that patients who are prescribed Migril tablets should take no more than four tablets for any single migraine attack and no more than six in any one week. Because there have been occasional reports of severe toxic effects from overdosage, the Council advises pharmacists to ensure that patients are aware of the maximum dosage.

The USA case of *Riff v Morgan Pharmacy* (1986) 508 Pa Super Ct A 2d 1247 is a similar case and illustrates the USA courts’ changed approach with regard to pharmacists’ responsibility to warn patients about medicines. In this case the jury’s verdict was upheld on appeal, awarding 65% fault against the pharmacist for not warning a patient against the maximum dosage for the dangerous and potentially toxic migraine medicine, namely Cafergot® suppositories. The pharmacy dispensed the medication with the prescriber’s directions on the label to use one per 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.
Adverse effects:

Pharmacists’ legal duty to warn a patient of adverse side-effects of prescription medication was considered in the Texas case *Morgan & Pettus v Wal-Mart Stores* (2000) Tex App 5282. In this case the jury found the pharmacy negligent in failing to warn of the adverse effects of the medicine desipiramidine after it was prescribed to a 12-year old boy for Attention Deficit Hyperactivity Disorder (ADHD). The boy developed a necrotic lymph node and died in August 1993, the autopsy report concluding that he died from hypereosinophilic syndrome, a rare side-effect of desipiramidine. The pharmacy subsequently appealed the decision. The Court of Appeal noted that, in previous cases where the courts held that a pharmacist had a duty to warn, the decisions were based on some ‘usual fact situations’ such as well-known and established adverse reactions or contraindications that would (and should) alert a ‘reasonable prudent pharmacist to a potential problem’. The court recognised the pharmacist’s changing role in patient care and noted technological advances available to detect potential drug interactions. However, the court concluded that ‘….. pharmacists have no generalised duty to warn patients of potential adverse reactions to prescription drugs absent some special circumstances not present…….’ In this case the Court held that the pharmacist was not negligent as the adverse drug effect was obscure and uncommon and most pharmacists did not know or could not have known about it. Therefore, it was not appropriate to make the pharmacist liable for failing to warn about such a rare adverse effect.

The court likewise in *Kasin v Osco Drugs* (2000) 200 Ill App 242 ruled that a pharmacy was not guilty as it only warned of common side effects and didn’t include renal failure, which was not a common side-effect of the prescribed drug Daypro®.

Addiction:

Pharmacists’ duty to warn patients of the potential risk of addiction was highlighted in the case of *Lasley v Shrake’s Country Club Pharmacy, Inc.* (1994)
880 Ariz Ct App P 2d 1129. In this case the patient was dispensed an addictive medication for thirty years, without the pharmacy ever informing the patient of the medicine’s addictive nature. The court determined that a question existed as to whether a pharmacist’s reasonable standard of care included a duty to warn of adverse side-effects. The court held that a pharmacy owes the patients a duty to take reasonable care and that failure to warn might constitute a breach of that duty.

**Contraindication:**

Pharmacists’ legal duty to warn the doctor or the patient about a contraindication was demonstrated in the USA case of *Heidi Happel v Wal-Mart Stores Inc.* (2002) 766 Ill NE 2d 1118. The patient was prescribed and dispensed Toradol®, with active ingredient the non-steroid anti-inflammatory drug (NSAID) ketorolac. Despite the fact that the patient previously reported her allergy to other NSAIDs and that this was entered into the pharmacy’s computer system, the medication was dispensed and labelled without a warning statement. The patient subsequently suffered an anaphylactic shock and sustained serious, ongoing disabilities. In reaching its decision, the court took the view that the pharmacist’s duty to warn did not require the pharmacist to either make a medical judgement or to intrude in the doctor-patient relationship, and thereby found that the pharmacist was guilty of negligence.

The 1990 case of *Dooley v Everett et al.* (1990) 805 Tenn App SW 2d 380 demonstrates the importance of keeping proper records during dispensing to be able to identify interactions and avoid litigation. The case dealt with whether a pharmacist has a duty to warn a patient or physician of the potential interaction between two prescription drugs, theophylline and erythromycin, which resulted in a child suffering cerebral seizures from the toxic levels of theophylline in his blood. On appeal the court examined expert testimony specifying that ‘pharmacies maintain a patient profile system, which should be reviewed by the pharmacist prior to filling a new prescription,’ including a determination of whether a drug interacts with any other drug currently ordered for the patient.
The court relied heavily on an affidavit by a practising pharmacist and community pharmacy owner, who further testified (Sweet et al., 2004 p. 389):

The standard of care also required the pharmacist alerted to the interaction to call the erythromycin prescriber, alert him or her to the potential interaction, and/or advise the patient or patient’s representative of the potential interaction and encourage him or her to (1) have his or her serum theophylline levels monitored and/or (2) be alert for side effects of theophylline toxicity. It is difficult to articulate what the standard of care requires of a pharmacist without knowing the exact circumstances under which the prescription for Ery-Ped® was presented but, regardless of the circumstances, the pharmacist is required to alert the patient or patient’s representative to the potential interaction.

Similarly, the 1996 Michigan Courts of Appeal case of Baker v Arbor Drugs (1997) 544 Mich App NW 2d 727 dealt with a pharmacist’s responsibility to detect drug interactions. The patient suffered a stroke due to a drug-drug interaction between tranylcypramine, which was prescribed for depression, and medicine prescribed for a cold. The cold medicine was dispensed at the same pharmacy where the patient’s tranylcypramine prescription had been refilled only seven days earlier. As became evident at trial, the pharmacy’s computerised drug-drug interaction program had been turned off, and the interaction went undetected. On appeal, the pharmacy was found negligent as it had voluntarily assumed the duty of care when it implemented and advertised the new computerised drug detection system to the public, claiming the system prevented harmful drug interactions.

These cases demonstrate the potential approach that would be taken by an Australian court in negligence claims involving pharmacists’ duty to provide appropriate advice to patients, and to contact prescribers about contraindications during dispensing.

**Responsibility to provide written information**

An issue that became evident through the interview analysis is the inconsistency with which CMI leaflets were issued. In addition, of the pharmacists who did issue CMI leaflets according to the guidelines, not all of them used these as counselling tools.
The importance of issuing CMI leaflets has been reinforced by the latest guidelines released by the PSA in 2007, which require of pharmacists to provide CMI leaflets even in cases when the prescriber had indicated that a CMI should not be supplied. The guidelines state that pharmacists are strongly advised against withholding CMI leaflets and recommend the provision of leaflets in the following instances (2006a, p. 369):

- When a medicine is first provided to the patient;
- When brand substitution occurs and it is deemed appropriate;
- When the dosage form has been changed;
- With each supply of medicine for which regular reinforcement of information may be required;
- At the request of the patient/carer;
- When the patient has special needs;
- At regular intervals for medicines used for long term; and
- When the pharmacist has received advice that a sponsor has made significant changes to the CMI.

CMI leaflets are useful resources for pharmacists in the counselling process. While they do not replace counselling or reduce pharmacists’ duty to advise patients about medicines, they should be used to support verbal counselling. Similar to the interview analysis, a 2005 Sydney study indicated that many community pharmacists did not comply with the requirements to issue CMI leaflets (Koo et al.). The researchers examined the use of CMI leaflets by consumers after receiving medication from a pharmacy and found that in 86% of cases (n = 154) the CMI leaflet was inside patients’ medication boxes, placed there by the manufacturers, without the involvement of a pharmacist or other health care professional. This study indicated that pharmacists do not follow the requirements and often issue a CMI leaflet without using it as a counselling tool.

The Medicines Information to Consumers (MIC) program was an initiative under the Third Guild Government Agreement, which provided pharmacists with an incentive to use CMI leaflets in practice, and they were paid 10 cents per prescription when a CMI was provided. Under the Fourth Agreement, this amount has been included in the dispensing fee and pharmacists are automatically paid to provide CMI leaflets. It is therefore assumed that CMI
leaflets are provided according to the guidelines and a greater responsibility has now been placed on pharmacists to issue CMI leaflets when appropriate.

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 USA case of *Cottam v CVS Pharmacy* (2002) 436 Mass 316, 764, NE 2d 814. In this case the Supreme Court found the pharmacy 51% 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 trazodone. 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.

CMI leaflets had been criticised as not being user friendly and research has shown how patients often misinterpret the information included in CMI leaflets about medicine side-effects (Berry *et al.*, 2002). However, following legal opinion sought by the PSA (2007), pharmacists are strongly advised against withholding CMI leaflets. These recommendations introduced new complexities and emphasise the importance of proper records regarding the supply of CMI leaflets to protect pharmacists against potential legal action. However, research highlighted that community pharmacy dispensing software programmes had not changed to reflect additional CMI requirements (Peterson *et al.*, 2003), an issue that needs to be discussed with software providers as part of a risk management strategy.
INCIDENT RECORDING

The ability to identify and improve patient safety measures is dependent on the management and recording of medication incidents by community pharmacists. Incidents were categorised by the researcher as:

1. A pharmacy intervention such as issuing of a CMI leaflet or other counselling tool, identifying an interaction, identifying an inappropriate prescribed medicine or dose or identifying a medication allergy;
2. A near miss (refer to Glossary for definition); and
3. A dispensing error (refer to Glossary for definition).

The recording of interventions, near misses and errors should be part of community pharmacists’ risk management and recording of pharmacy incidents is critical to the profession because it:

- Provides a medico-legal record;
- Facilitates the provision of quality care and continuity of care; and
- Enables quality audits and peer review.

However, of the 17 pharmacists interviewed, only three indicated that they recorded interventions, but not on a continuous basis. This outcome is similar to previous research which found that the recording of Australian community pharmacist interventions had been virtually non-existent (Peterson et al., 2003). This is also the case in the UK and Gross (2001) commented that community pharmacists in the UK regularly make interventions during the dispensing process but few actually document their interventions, mainly due to time constraints.

None of the participants kept a record of near misses, hence reducing the educational value of near misses. Actual errors were mostly only recorded when it was considered to be of a serious nature, for example, when Guild Insurance was contacted. This outcome is similar to Tasmanian research that indicated that the number of dispensing errors occurred were well above those
reported to regulatory authorities or professional indemnity insurance companies and seemed to be accepted as part of practice (Peterson et al., 1999). Similar UK research indicated a very low likelihood of reporting of errors by community pharmacists (Ashcroft et al., 2006). This is despite the fact that the UK has a system in place through the National Reporting and Learning System (NRLS), that is designed to co-ordinate the reporting of patient safety incidents nationally.

The Pharmacy Recording of Medication Incidents and Services Electronically (PROMISE) intervention study highlighted the benefits of using an efficient documentation system. This 2002 study involved 19 community pharmacies in Tasmania that tested a documentation system that was developed to integrate with dispensing software (Peterson et al., 2003). The study showed that when computerised dispensing systems contained automated education alerts, there was a significant potential for increasing pharmacist intervention rates, and thereby improving the QUM. A Swedish study that involved 45 community pharmacies similarly indicated positive pharmacist behaviours through the use of electronic documentation (Westerlund et al., 2003). These behavioural changes included listening more carefully to patients, asking more questions and discussing more information with them.

The changed role of community pharmacy now requires a pharmacist to review patients’ medication for appropriateness and intervene when necessary. The recording of interventions is therefore crucial to protect pharmacists against potential litigation. However, the interview analysis indicated poor recording of interventions, indicating that pharmacists need to learn to adequately document, monitor and review the patient care provided by them. The results also indicated that dispensing software programs need to be upgraded to support the changed role of pharmacists and facilitate the recording of all interventions. The results further indicated that many community pharmacists do not realise the medico-legal value in the recording of these incidents – a matter that has to be addressed in order to improve risk management strategies as pharmacy records are essential in the protection against negligence claims.
The most efficient and effective way for pharmacists to routinely record interventions would be at the time of dispensing. However, there is not currently any Australian pharmacy standard that specifies how interventions should be recorded or that pharmacists are even required to record dispensing interventions. The Professional Practice Standard for dispensing merely requires that all interactions with prescribers should be documented on the prescription and in the dispensing record (Pharmaceutical Society of Australia, 2006c).

The recording of interventions can be either in electronic format or hard copy, with electronic recording more effective. However, dispensing software programs have often been criticized as not being user-friendly with regard to the recording of interventions (Gross, 2001). The poor recording of interventions by the interview participants supports these claims. In addition, dispensing software programs do not provide an audit trail, which was demonstrated by the disciplinary case that involved the supply of methotrexate tablets. The Board records for this case stated that:

In this matter there is no evidence that either Mr or Mrs ** were provided with written advice about the dose, day and time of administration for methotrexate – other than the instructions on the label placed on the outer packaging.

The pharmacy in this case had no record of using counseling tools or whether one or two labels were printed – one for the primary container and one for the outer packaging. This case demonstrates the inability of dispensing software to provide an audit trail, which should be a crucial part of community pharmacy’s risk management.

In order to improve community pharmacists’ risk, it is crucial that they realise the importance of the recording of all medication incidents. Additionally, computer software programs need to be upgraded to reflect the changed demands on pharmacists, and facilitate incident recording.

**SUMMARY**
The analysis indicated that community pharmacy practice is a high-risk setting and that the changed role of pharmacists has significantly impacted on pharmacists’ risk and potential legal liability. Various issues contributing to this risk were identified, indicating the importance of managing these services, and that workflow and practice tools be reviewed and managed on an ongoing basis.

5.4 PHARMACY SUPPORT STAFF

The appropriate use of pharmacy support staff has many advantages, including the release of pharmacists to focus on patient care services. However, the interview analysis indicated that many pharmacists do not use support staff in a way that releases the pharmacist. Instead of using support staff for technical functions, many of the interviewed pharmacists allocate them to provide patient care services. The support staff in these pharmacies are trained to mainly refer patients to pharmacists when, according to the support staff’s judgement, it is necessary. This was the case with both the provision of advice regarding dispensed medicines and with determining the appropriateness and giving of advice regarding the supply of most OTC medicines. The practice of utilising support staff to provide counselling services instead of preserving this function for pharmacists affects the quality of patient care services. It also causes increased risks, as support staff do not have the clinical knowledge that is required to make professional judgements.

The analysis indicated that the role and use of pharmacy support staff not only impact on the effectiveness of community pharmacists to provide patient care services, but also impact on their overall risk exposure and management.

TRAINING AND SCOPE OF PRACTICE

Recognised community pharmacy support staff qualifications are Certificates I, II, III and IV in Community Pharmacy. These qualifications are offered as vocational training programs in accordance with the National Competency
Standards for Pharmacy Assistants, and form the basis of the National Community Pharmacy Training Package. In order to improve consistency across the industry, the QCPP was revised, and requires that all staff handling scheduled medicines be trained in a recognised course. This requirement will come into force on 1 March 2008 (Pharmacy Guild of Australia, 2006c). The training modules are yet to be finalised and accredited. However, as previously discussed, QCPP accreditation is voluntary and the training is therefore not a legal requirement.

In order to improve the quality of community pharmacy services with regard to the supply of medicines, the training of all staff handling medicines should be mandatory, as is the case in both the United Kingdom and New Zealand (Goodman, 2006b). To ensure consistency across jurisdictions, the mandatory training of support staff is therefore an issue that needs to be addressed by the pharmacy registering authorities through the Australian Pharmacy Council.

Three broad categories of support staff are involved with direct patient care in community pharmacy, namely: dispensary assistants, pharmacy assistants, and retail staff. These staff are involved in many aspects of community pharmacy practice under the guidance and supervision of pharmacists. Although state and territory drugs and poisons legislation addresses the handling of scheduled medicines, the legislation does not specify what pharmacy support staff are entitled to do, but rather include only very generalised statements. For example: in Queensland the Health (Drugs and Poisons) Regulation 1996 does not refer to the role of support staff at all in assisting pharmacists with dispensing functions. Section 258 of the Regulation does authorise pharmacy assistants to sell S2 medicines at a dispensary. A pharmacy assistant is, in the Regulation, defined very broadly as ‘a competent adult employee’. The Queensland legislation is therefore not specific in terms of the scope of practice of support staff.

Indeed, research conducted in 2004 identified a grey area regarding the scopes of practice of pharmacy or dispensary assistants. The research identified that only Queensland and Victoria had guidelines regarding the use of dispensary
assistants in the dispensary (Kinrade, 2004). The Queensland guidelines are in the form of the Pharmacists Board of Queensland *Guidelines regarding the use of dispensary assistants*, which states that the Board recognises dispensary assistant training offered by the Guild, the PSA, and the SHPA (Pharmacists Board of Queensland, 2006). The policy highlights pharmacists’ responsibility in supervising dispensary assistants and states the following limitations applying to the duties of dispensary assistants, namely that they SHOULD NOT (p. 2):

- do patient counselling;
- issue dispensed medicine or Pharmacist Only medicine unless checked, authorised and approved by a pharmacist;
- receive prescriptions by telephone;
- authenticate prescriptions;
- interpret prescriptions;
- make decisions regarding generic substitution on prescriptions; and
- make other clinical judgements.

The policy is specifically aimed at dispensary assistants, and the Board does not have a policy regarding the use of other pharmacy support staff, such as front shop assistants. However, the Regulation does, by default, require of pharmacists to provide medication counselling. The PSA has a policy on the use of dispensary assistants that specifies the circumstances in which they may be used, with an overall objective of promoting the use of dispensary assistants to complement the pharmacist’s roles and duties, while ensuring that they do not undertake activities requiring the knowledge and professional judgements of a pharmacist (Pharmaceutical Society of Australia, 2006a).

In November 2004 the Australian Pharmacy Council identified the need for support staff guidelines, and a recommendation was made specifying that pharmacy registering authorities had to develop support staff policies (Bell, 2005; Goodman, 2006b). The recommendation reflected the Council members’ agreement that it was part of the interests and responsibilities of pharmacy registering authorities to develop the role and competence of non-pharmacist staff assisting in the provision of pharmacy services. However, despite this recommendation, there still is a lack of regulatory guidelines – an issue that needs to be addressed.
A lack of consistent workflow is another issue identified through the interview analysis. Many dispensing workflow models and function allocations are used and applied by pharmacists, with a large degree of variability. Therefore, there is a need to develop community pharmacy workflow models to guide the profession, specifically with regard to the utilisation of support staff in the dispensing of prescriptions.

As the profession evolves into patient care, extended roles for support staff need to be created. This has already been introduced in the UK with accredited checking technicians who may perform certain dispensing functions, thereby releasing pharmacists to provide patient care activities (Royal Pharmaceutical Society of Great Britain, 2005). The changed role of pharmacists and the increasing reliance on pharmacy technicians in the UK are also evidenced in recent pronouncements by the Royal Pharmaceutical Society of Great Britain and amendments to the Society’s Code of Ethics and particular practice standards (Royal Pharmaceutical Society of Great Britain, 2006b). The extended use of support staff is, however, an area that still needs exploring by the Australian pharmacy profession.

**Responsibility and Liability**

Pharmacy support staff work under the supervision of pharmacists. Different levels of supervision exist, which can be broadly categorised into direct and indirect supervision. In a community pharmacy set-up, ‘front shop’ support staff work mostly under indirect supervision, whereas dispensary assistants work under direct supervision. The level of pharmacist involvement in the front shop is mostly determined by the schedule of the medicine, as legislation requires of pharmacists to be involved in the supply of S3 medicines. However, the interview analysis indicated that many pharmacists have a ‘tick-in-the-box’ practice in regard to S3 supplies, and often do not gather the necessary information from patients themselves. As previously discussed, there also needs to be a shift towards taking into consideration the patient’s needs with all OTC medicines. Current practice focuses on the product and not on the
patient, whereas the patient’s risks need to be considered in the referral process.

Pharmacists are required to set up systems to ensure appropriate referrals from front shop staff. A recent study by Patterson et al. reported the findings of a qualitative study of medical receptionists and the liability of general practitioners for the actions of their employees. The study identified a need to ensure receptionists do not undertake activities that place the general practitioner at risk (Patterson et al., 2005). Similarly, pharmacists need to ensure that support staff have, and are familiar with protocols and know when to refer patients to reduce the pharmacist’s liability in case of an adverse incident. Otherwise pharmacists will be vicariously liable for the negligence of support staff, which liability applies to health care employers who may have the primary responsibility for paying legal claims arising from negligent patient care (Tito, 1994).

However, support staff may be held responsible if policies and procedures are in place, but not followed. In 2002 the Disciplinary Committee of the Pharmaceutical Society of New Zealand dismissed charges against two pharmacists after determining that all reasonable precautions had been taken (Pharmacy Interactions, 2003). In both cases the pharmacies had policies and procedures in place to deal with the appropriate sale of S3 medicines, and the pharmacist could show evidence that staff were aware of, and trained in, those policies and procedures.

Therefore, pharmacy support staff have a responsibility to refer at risk patients to the pharmacist. This responsibility will potentially be similar to the duty of care required by a nurse practitioner or doctor’s receptionist, as identified by the new South Wales Court of Appeal in Alexander v Heise [2001] NSWCA 422. In this case the Court held that:

… a doctor’s receptionist has a duty of care to assess a patient’s condition, determine the urgency of the case and make an appointment based on the circumstances and urgency of the patient’s symptoms.
Similarly, dispensary assistants have a responsibility to follow the pharmacy’s dispensing protocols. Although there has been no Australian case law to illustrate this responsibility, a recent New Zealand case demonstrates the court’s approach and Australian courts would probably follow a similar argument (New Zealand Health and Disability Commissioner, 2006). This case involved a dispensing error that resulted in a two-and-a-half year old girl being admitted to hospital after taking Risperdal® (risperidone) syrup, an antipsychotic instead of Redipred® (prednisolone) syrup, which is a corticosteroid. The technician mistakenly selected Risperdal® from the dispensary shelf and poured it into the dispensed bottle. A bottle of Redipred® was also picked to fill the dispensed bottle to the required quantity. Although the pharmacy’s standard operating procedure stated that ‘containers are to be left beside dispensed medicines until after checking procedure’, the technician did not follow this procedure but instead discarded the Risperdal® bottle, only leaving the Redipred® bottle next to the bottle of dispensed syrup. When the pharmacist subsequently checked the dispensed bottle, she unwittingly approved an unsafe dispensing. Following an investigation by the Health and Disability Commissioner, the Commissioner found that there was a breach of the Code of Health and Disability Services Consumers’ Rights by the technician, in that the dispensing service was not provided with reasonable care and skill. The technician has been referred to the Director of Proceedings for the purpose of deciding whether any proceedings should be taken.

This case demonstrates both support staff’s responsibility to follow processes and procedures, and pharmacists’ responsibility to ensure that support staff are trained in the correct procedures. In the case of an error, the pharmacist needs to be able to prove that processes and procedures were in place, but not followed. If that is the case, support staff would potentially be held liable for not following practice policies and procedures.

It is important that both pharmacists and support staff are aware of their responsibilities. However, very little has been published about roles and responsibilities, and potential liability issues also need to be communicated both to pharmacists and support staff on an ongoing basis.
REGISTRATION

The evaluation of the pharmacy regulatory requirements indicated that none of the pharmacy registering authorities currently maintains a register of support staff. However, the registration of support staff not only provides for better recognition of their roles, but also creates statutory control. The changes to the regulatory and professional structures in the United Kingdom will *inter alia* introduce mandatory registration for pharmacy technicians (Middleton, 2007). Mandatory registration of support staff is also being considered in other developed countries (Healthcare Management Advisors Pty Ltd, 2004).

Registered support staff should be subject to disciplinary action in the same way as pharmacists when not following proper procedures (Middleton, 2007). The Australian pharmacy registering authorities should therefore consider mandatory registration of support staff, as there is currently an imbalance between the functions allocated to support staff in community pharmacies and the degree of control over them, which increases pharmacists’ risks. As previously discussed, the authorities also need to develop proper guidelines for pharmacists regarding the use of support staff.

SUMMARY

Various issues were identified that indicated a need to review the utilisation of pharmacy support staff. These included the need to develop scopes of practice, to clarify responsibilities and liabilities, and to register support staff. These issues need to be considered by pharmacy registering authorities and professional organisations, as the release of pharmacists to provide patient care services is dependent on the proper utilisation of appropriately trained support staff.
5.5 APPLICATION OF RESEARCH FINDINGS TO QUALITY AND RISK MANAGEMENT

The purpose of the study was to examine the risk management procedures in community pharmacy practice, with specific reference to the expanded role of pharmacists. The study was exploratory and analysed data gathered through three methods: an analysis of the Pharmacists Board of Queensland disciplinary processes and outcomes; an analysis of interviews with community pharmacists; and a comparison of the pharmacy practice regulatory requirements throughout Australia.

An integral part of risk management is the analysis of the potential for risk and then designing the systems and processes that address and alleviate potential negative outcomes. The Australian/New Zealand Standard: Risk management, which provided an excellent framework to design a risk management process, was combined with Donabedian’s structure-process-outcome theory to build a framework applicable to community pharmacy risk management.

The first step was to establish the context within which community pharmacy is practised. One of the major factors that were considered was the changing role of pharmacists towards taking a bigger responsibility regarding patients’ medication management. The regulatory framework, which is the structure within which the profession operates, supports this role through the legislation and delegated legislation applicable to pharmacy practice. However, the interview analysis indicated that pharmacists do not necessarily integrate the practice standards and guidelines in their everyday practices. In addition, the analysis of the various interstate regulatory requirements indicated that there are considerable differences between jurisdictions that impact on the practice of pharmacy and risk management procedures.

With regard to identifying, analysing and evaluating risks, two processes were focused on to gather the information:
1. The study of the disciplinary cases provided a wealth of information regarding practice risks and those situations in which pharmacists did not manage the risks, which in many instances caused a negative outcome for patients. The cases not only provided information on the types of errors that lead to disciplinary action, but also the way in which the Board utilises practice resources to determine what should be the appropriate standard of care.

2. The interview analysis provided in-depth information regarding pharmacists’ knowledge of practice risks and their reaction to and management of identified risks. It provided in-depth knowledge of contemporary practice and highlighted the areas that need to be addressed to reduce pharmacists’ risk.

5.6 LIMITATIONS OF THE STUDY

In addition to the methodological limitations listed under Chapter 3 in section 3.6, the following limitations apply to the overall study:

- The analysis of incidents reported to the Pharmacists Board of Queensland focused on those cases that proceeded through to disciplinary actions, and did not include all cases reported to the Board that underwent investigation. There is no doubt that if the study was broadened to include investigations, more would be known about the Board's disciplinary process.

- The analysis did not include cases reported to the Health Quality and Complain Commission. At the time of the data collection for this thesis, the inclusion of HQCC data was considered by the researcher but the Commission was not well established at that state. However, future research should include the HQCC processes and cases.
The analysis did not include an evaluation of the incidents reported to Pharmaceutical Defence Limited. Although the researcher attempted to obtain detailed information from Pharmaceutical Defence Limited and/or Guild Insurance, this was not provided but only a very brief summary of Queensland incidents over a twelve month period.

The community pharmacists interviewed were mainly those who had completed the expression of interest forms. Those pharmacists who responded were probably more likely to follow good practice standards. Accordingly, the information gathered through the interviews does not represent the population of Australian community pharmacists, but rather those pharmacists who were willing to be interviewed, and thus the frequency of reporting of best practice may be overestimated.

The sampling did not include big banner groups and the findings may therefore not apply to this category of pharmacies.

The study did not include extended services provided by pharmacists, such as clinical pharmacy, the preparation of extemporaneous products/extemporaneous dispensing, the packing of Dose Administration Aids (DAA) and the provision of Home Medicine Review (HMR) and Residential Medication Management Review (RMMR) services. Community pharmacy risk management strategies need to incorporate these services, as they require unique approaches.

The study did not include consumer views about the changed role of pharmacists and their perception of the quality of the services provided by community pharmacists. Such an insight may assist in understanding the impact of these changes, particularly as they relate to risk management.
• The comparison of the regulatory differences between the jurisdictions did not include an analysis of the various drugs and poisons legislation in place, which would cause further regulatory inconsistencies.
CHAPTER 6 – CONCLUSION

6.1 IMPLICATIONS OF THE FINDINGS

The findings of the research are significant with the potential to assist the profession to initiate reforms aligned with the changed role. A number of implications are highlighted below as recommendations that impact on pharmacy regulation and risk management practices.

Recommendations – Pharmacy regulation

The findings indicated that there is a dearth of research in relation to the legal liability of pharmacists in the Australian context. The regulation of the profession is diverse throughout Australian jurisdictions and, in many instances, does not reflect the changed role of pharmacists. On that basis the following recommendations are made:

- There needs to be a focus on harmonising state and territory legislation to ensure more consistent registrant licensing requirements (continuous professional development), pharmacy practice and premises requirements. Such harmonisation will improve the provision of consistent practices and patient outcomes as well as contribute towards smooth processes to implement national registration for pharmacists;
- Pre-registration training and assessment should be standardised, the training of pharmacist preceptors should be introduced and guidelines developed for the approval training sites. The Queensland pre-registration assessment should specifically be reviewed;
- Pharmacy registering authorities, through the Australian Pharmacy Council, should play a more active role in standard setting with the professional organisations and standardise the utilisation of practice standards and disciplinary definitions and processes;
• Dispensing workload norms need to be set that reflect practice advances and the utilisation of dispensary assistants;
• More detailed information needs to be provided to registrants regarding disciplinary outcomes, thereby using these as teaching tools;
• Scopes of practice for the various levels of pharmacy support staff should be developed with a focus to release pharmacists to provide patient care services, and legislation should subsequently be amended;
• Pharmacy support staff involved in the supply of S3 and S2 medicines and dispensing should be registered to reflect their responsibilities and provide a mechanism to discipline unprofessional conduct;
• The Pharmacists Board of Queensland should focus on following consistent processes when dealing with disciplinary cases and utilise practice standards and guidelines consistently in the decision-making process;
• The Pharmacists Board of Queensland has to review communication strategies to registrants so that they become more familiar with Board policies and procedures;
• A need was identified for Pharmaceutical Defence Limited to publish incident data to improve risk management in community pharmacy; and
• A step-wise approach should be followed to gradually introduce national registration, as recommended by COAG.

Recommendations – Practice risk management

The findings indicated that pharmacists frequently failed to adhere to best practice, specifically in regard to their advisory role. The recommendations from this study as to practice risk management are as follows:

• Dispensing and OTC medicine supply and dispensing workflow models need to be developed that focus on the appropriate use of
pharmacy support staff to release pharmacists to provide patient care services;

- Dispensing software programs need to be upgraded to enable more efficient intervention recording and also provide an audit trail;
- Ongoing education should be provided, directed to the safety of OTC medicines with a patient rather than a schedule focus;
- The professional practice standards should be reviewed and simplified and ongoing education directed at the implementation of the standards in practice to improve the quality of services and risk management practices should be provided;
- The Guild should review the QCPP assessment process and should publish information about non-compliance with QCPP accreditation standards to improve current standard of practice; and
- Pharmacists should be educated about their changed legal liability and potential risks involved in the changed role should be highlighted to assist them in the development of risk management practices, specifically in regard to the recording of interventions.

6.2 IMPLICATIONS FOR FUTURE RESEARCH

This study showed that there is a dearth of information regarding the impact of regulatory requirements on community pharmacy; the potential legal liability of the changed role and demands placed on pharmacists; and community pharmacy risk management processes. This study highlights the need to conduct further research, specifically focusing on the following:

- A comparison of the various drugs and poisons legislation in place throughout the jurisdictions, which comparison has to be integrated with the pharmacy practice regulatory requirements identified through this study;
- The development of tools to evaluate the information and advice provided by pharmacists and pharmacy staff with regard to both
prescription and OTC medicines and the management of minor ailments;

- An analysis of the regulatory requirements and risk management procedures implemented by pharmacists in the provision of extended services, such as the packing of dose administration aids, extemporaneous compounding and the provision of medication management services.

### 6.3 CONCLUSION

This study demonstrated that Australian community pharmacists accept an increased responsibility towards the provision of patient care services. However, the analysis identified regulatory shortcomings to support and enforce this changed role. Pharmacy regulation throughout Australia is diverse with the various pharmacy registering authorities operating under different statutory models. These differences potentially impact on practice processes and procedures implemented by community pharmacists, and the pharmaceutical services they provide.

Various models of co-regulation exist between the registering authorities and the pharmacy professional organisations, and professional self-regulation inconsistently applies throughout jurisdictions. Therefore, national registration, as recommended by COAG, is desirable as it will facilitate regulatory harmonisation. However, due to the many jurisdictional inconsistencies, this process needs to be slow to enable the pharmacy registering authorities to systematically work through the required processes needed to implement change.

The profession has played an active role in developing professional practice standards and guidelines reflecting the changed role of community pharmacists. The absence of the pharmacy registering authorities in the development of the standards creates risks for pharmacists as the standards are used in disciplinary proceedings. Additionally, a significant proportion of the authorities
are not proactively involved in auditing the implementation of the standards and the monitoring of community pharmacy services.

Disciplinary cases demonstrate the pharmacy registering authorities’ approach towards pharmacists’ responsibility, and international case law demonstrates increased pharmacist legal liability. This expansion of the judicial recognition of pharmacists’ responsibilities towards patient care services should not be seen as a threat, but rather as a positive development, as it reflects the realities of current pharmacy practice. Community pharmacists need to more actively develop processes and procedures regarding the various medication management services they provide, as these services require of them to spend more time with patients.

In summary, the changed role of community pharmacists places an increased liability risk on pharmacists. This risk needs to be managed, and many processes in community pharmacy practice need to be reviewed in order to ensure that appropriate risk management practices are in place. Community pharmacists should continually carry out risk assessment to minimise the likelihood of disciplinary action and negligence claims. Additionally, the regulation of community pharmacy has to be reviewed to ensure the legislation reflects the changed role and responsibilities of pharmacists and pharmacy support staff and practice developments.

Pharmacy is keen to develop and promote a range of new health management services and become a more visible contributor to primary healthcare in Australia. However, before introducing new services it is important to ensure that quality services and appropriate risk management processes are in place with regard to contemporary core services, such as the dispensing of prescriptions and the provision of patient advice.
APPENDICES

APPENDIX 1: DISPENSING PROFESSIONAL PRACTICE STANDARD AND SUMMARY OF S2/S3 STANDARDS.

5. Dispensing

**Standard:** The pharmacist ensures that dispensing occurs accurately, reflects the prescriber’s intentions, and is consistent with the needs and safety of the consumer.

**Scope of this standard**

- Legislative requirements are not addressed in this standard. It is assumed that pharmacists will comply with required Commonwealth/State/Territory legislation in the provision of this service.

- This standard applies to the dispensing of prescription medicines and to products prepared extemporaneously. The focus of this standard is primarily on receiving the prescription, assessing it against consumer needs and safety, and accurately supplying the medicine.

- Pharmacists are reminded that this standard is to be applied in conjunction with the Fundamental Pharmacy Practice and Counselling standard. Refer also to the Counselling, Compounding and Dose Administration Aid Service standards where appropriate.
Criterion 1  The pharmacist is aware of systems of good dispensing practice and can implement them.

Indicator 1  Applies and supervises a documented dispensing procedure.
2  Ensures a copy of the dispensing procedure is available in the area where dispensing takes place.

Notes
A systematic approach to dispensing is highly recommended. Each pharmacy should have a dispensing procedure that addresses the three phases of the dispensing process:
- before dispensing;
- preparation phase; and
- provision of the medicine.
Flow charts could help to illustrate the processes involved.
A pharmacy technician may carry out the functions of assembling medicines and data entry. However, the pharmacist is responsible for assessing the appropriateness of the medications in relation to the full medication history (or medication profile if available), the final check of dispensed medicines, and the counselling of the consumer.
Where the pharmacy employs bar code scanners in the dispensing process, the scanning procedure should be used just before the label is attached, to confirm the selection of the correct medicine, rather than using the bar coded information as a source of data entry.

Criterion 2  The consumer’s known drug allergies and sensitivities are routinely determined, recorded and taken into account when dispensing a medicine.

Indicator 1  Establishes any allergies and sensitivities known to the consumer and records them in the medication history file.
2  Systematically uses alerts to identify the consumer’s known drug allergies and sensitivities.
3  Reviews the consumer’s medication history for known drug allergies and sensitivities before a medicine is dispensed.

Criterion 3  The consumer’s medication history is adequately reviewed and updated before dispensing medicines.

Indicator 1  Reviews and considers the possible multiple sources of medicines (prescription and non-prescription), and the influence of relevant disease states on the action and/or effect of prescribed medicines.
2  Records all dispensed medicines in the consumer’s medication history.
Notes

The pharmacist is encouraged to record in the medication history all medicines that the consumer is taking, including prescription and non-prescription medicines, vitamins and other dietary supplements and complementary medicines. A comprehensive medication profile is the basis for assessing the appropriateness of the current prescription and for monitoring both adverse drug reactions (ADRs) and drug interactions.

Criterion 4  Clinically significant drug–drug, drug–food and drug–disease interactions, precautions and contraindications are checked and accounted for when a prescription is dispensed.

Indicator 1  Accesses current information on clinically significant interactions, contraindications, precautions and disease states.
            □

2  Reports clinically significant adverse drug reactions (ADRs) to the Adverse Drug Reactions Advisory Committee (ADRAC) where appropriate.

Notes

The pharmacist should be mindful of potential ADRs when dispensing a prescription. The pharmacist should ask about the consumer’s previous experience with the medicine and, where necessary, provide advice about potential ADRs. The pharmacist should provide advice that is consistent with, and complementary to, the advice given by the prescriber or relevant health professional.

The prescriber may need to be contacted to discuss an ADR or to identify an alternative approach that will prevent or minimise the ADR. When speaking of ADRs with either the prescriber or the consumer, it is important to distinguish side-effects of medicines from drug-induced allergic (hypersensitive) reactions, both of which are ADRs. Pharmacists should be aware that consumers might speak of side effects of drugs when asked about their known drug allergies.

The pharmacist is expected to check for drug interactions each time a prescription is dispensed. Professional judgement must be used to assess which drug interactions are clinically significant, as there are many drug interactions that have insignificant effects on the expected therapeutic outcome. The pharmacist should be particularly mindful of drug interactions whenever a consumer starts a new therapy or dosage form or ceases a drug or dosage form.

Criterion 5  When necessary, the pharmacist contacts the prescriber about a prescription, medicines and/or consumer issues.

Indicator 1  Documents on the prescription, and in the dispensing record, all interactions with a prescriber about prescriptions, medicines and/or consumer issues.
            □

2  Documents on the prescription, and in the consumer record, where possible, all changes to treatment regimen authorised by the prescriber.
            □

3  Applies a documented procedure to detect and appropriately address excessive or fraudulent prescriptions.
            □
Criterion 6  Due care is taken when dispensing oral cytotoxic medicines.

Indicator 1  Counts cytotoxic medicines using separate equipment that is made available and labelled for the purpose (e.g. a tablet counting tray and spatula).

Indicator 2  Ensures all cytotoxic medicines stored in the dispensary are labelled as such using supplementary labelling.

Notes

It is preferable to store all cytotoxic medicines separately in the pharmacy, and to clearly identify them as cytotoxic. A clearly marked counting tray and spatula should be dedicated to counting cytotoxic medicines. Consumers should be advised about the correct handling of cytotoxic medicines, particularly those in tablet form that are not film-coated. Cytotoxic medicines that are film-coated should not be broken.

Criterion 7  Labels of dispensed medicines are legible and unambiguous.

Indicator 1  Uses labels with clearly marked dark print.

Indicator 2  Gives special consideration to the needs of visually impaired consumers.

Indicator 3  Ensures the label contains complete and unambiguous directions for use.

Indicator 4  Uses ancillary labels to indicate specific usage instructions (e.g. “Shake the Bottle”).

Notes

The pharmacy label should not cover the manufacturer’s batch number and expiry date. Where a broken quantity is supplied, the manufacturer’s batch number and expiry date should appear on the label of the dispensed medicine. Labels and printed counselling advice may need to be enlarged for visually impaired consumers.

Criterion 8  Consumers are given complete dosing instructions for their medicines.

Indicator 1  Ensures all labels and records carry specific and complete instructions for use.

Indicator 2  Provides additional written medicine dosing instructions where required, and Consumer Medicines Information according to the guidelines.

Indicator 3  Adapts instructions for medicine use where necessary to address communication barriers such as literacy level, cultural background and language mastery.

Indicator 4  Non-prescription items written on prescriptions are treated in the same manner as prescription only items.
Notes

Where appropriate, the non-prescription item should be labelled with instructions from the prescriber, and pharmacists should provide the consumer with the appropriate level of counselling.

To minimise the risk of confusion for the consumer, the pharmacist should label generic prescription products with both the brand and generic names, preferably in equal font size.

Criterion 9  Consumers are given adequate additional instructions about using dispensed medicines safely and storing them properly.

Indicator 1  Uses appropriate ancillary labels on dispensed medicines as recommended in the Australian Pharmaceutical Formulary and Handbook.

Criterion 10  The pharmacist checks the dispensed medicine for accuracy.

Indicator 1  Ensures the dispensed medicine is in date for the expected duration of treatment.

2  Checks the dispensed medicine against the prescription before the medicine is supplied to the consumer.

3  Dispensing records show which pharmacist dispensed the medicine(s).

4  Initials the prescription label when the issuing pharmacist is not the dispensing pharmacist.

Notes

Where the pharmacist who physically issues the prescription to the consumer is not the dispensing pharmacist, it is good practice for the issuing pharmacist to initial the label while performing a final check before giving the medicine to the consumer.

Criterion 11  The pharmacist adequately identifies the consumer when supplying the medicine.

Indicator 1  Seeks confirmation of the consumer’s identity to ensure the correct medicine is handed to the correct consumer.

Criterion 12  The pharmacist ensures that all dispensing is completed in a timely manner.

Indicator 1  Routinely assesses current workload and the number of prescriptions received to determine the likely amount of time the consumer will need to wait.

2  Informs pharmacy staff and the consumer of the anticipated waiting time for the prescription.
Criterion 13  The pharmacist ensures the consumer fully understands the nature of brand substitution when it occurs.

Indicator 1 Informs consumers of less expensive brand substitutes where they are available and consistent with prescribers intent and desired health outcomes.  
Indicator 2 Records in the dispensing record and on the medicine label when brand substitution occurs.  
Indicator 3 Substitutes brands only where bioequivalence has been established and the consumer has consented.  
Indicator 4 Counsels the consumer about the nature of the substitution.

Notes

Where Pharmaceutical Benefits Scheme (PBS) brand substitution is allowed, the pharmacist should discuss brand substitution with the consumer, and with the prescriber if required. The consumer’s health should always be the pharmacist’s prime consideration in any decision about brand substitution. For details on brand substitution, refer to Guidelines on Pharmaceutical Benefits Scheme Brand Substitution.

Pharmacists should record the details of brand substitution. Consistency in the selection of brands for consumers on long-term therapy can reduce the possibility of consumer confusion. It may be beneficial to discuss the issue of brand substitution with the pharmacy’s principal prescribers to clarify that the prescribers understand the process of endorsing the prescriptions ‘no substitution’ where they have determined substitution would be disadvantageous to the consumer.

| Declaration (Self-assessment and declaration to be completed by all pharmacists providing this service) |
| Reasons why any indicators are marked 'not applicable' |
| Action to be undertaken for each indicator currently not met |

I have completed this assessment in a fair and ethical manner, and fulfilled the marked indicators in the provision of this service.

Signed ...........................................  Date ........................................
Additional information

The layout or design of the dispensary and the pharmacy general trading area should comply with State/Territory legislation including the Pharmacy Acts, and be conducive to providing an efficient dispensing service. It is desirable that:

- the dispensary is separate from the general trading area;
- consumers have clear access to a well-marked counter for receiving prescriptions;
- the pharmacy has a dedicated area that is conducive to consumer counselling; and
- there is a waiting area with seats for consumers.

Medicines should be stored in accordance with manufacturers’ requirements. Medicines that require refrigeration are to be stored in a refrigerator dedicated to pharmaceuticals. Medicines that require room temperature storage are to be stored in a cool place away from direct sunlight. Temperature monitoring systems should be used to ensure that the required temperature is maintained.

Pharmacists involved in dispensing ‘supervised therapies’, or in restricted supply circumstances such as benzodiazepine withdrawal or supervised antimicrobial therapy, should refer to the Optimal Substitution Program standard for additional information.

Information Resources


1b. How to read and use the standards

The following sample standard will outline the structure and intent of the information contained in the standards document.

**Short name of standard**

**Standard #.** A simple sentence that encapsulates what the standard covers

**Criterion #**

This statement describes ongoing actions that the pharmacy needs to do to ensure that a part of the Standard is being met.

**Indicator**

Required Actions & Behaviours:

1. These statements describe a number of actions you have to take and behaviours you need to adopt to ensure that you meet the associated criterion.

2. Typically these statements will ask you to Confirm, Develop & Maintain, Determine, or Provide.

3. As a self-assessment tool, you can use these boxes to either tick, cross or mark N/A (not applicable).

**Implementation Notes:**

*Materials available to assist in meeting the Criterion*

The materials are examples of Policies, Procedures and Tools you may use in order to meet the standard.

- POLICIES (POL) outline WHY a Standard is in place,
- PROCEDURES (PROC) outline HOW to do something required by the Standard and
- TOOLS provide templates for any additional documents that need to be developed in order to meet the standard.

These materials conform to minimum practice requirements. Individual pharmacies may choose to alter or augment these materials – however, the new or updated version must be no less rigorous than the sample provided.

Each Policy, Procedure or Tool is named using a 3-part system:

- letters referring to the type of document (POL, PROC, or TOOL)
- a number referring to the Standard it relates to and
- a letter referring to the position of the document within the Standard.

For example, the first Procedure associated with Standard 4 is 'Proc 4A'.

*Evidence required at Assessment*

- This section details the evidence required for assessment of the criterion. It will typically ask for 'Proof of' or an 'Explanation of' of a particular procedure or document.
- Some proof will be supplied by documentation; other proof will be obtained through observation.
- Additional proof can be gathered via performance in a pseudo-patient visit.
Summary of Standards

1. Resources

Standard 1
The pharmacy has adequate resources to consistently promote the quality use of Pharmacy Medicines and Pharmacist Only Medicines.

2. Staff training

Standard 2
All staff members who supply Pharmacy Medicines and Pharmacist Only Medicines receive initial and ongoing training on products, services, and procedures relevant to their supply.

3. Location and signage

Standard 3
Pharmacy Medicines and Pharmacist Only Medicines are located in areas of the pharmacy that indicate that they are not normal items of commerce, and are consistent with scheduling classifications.

4. Consumer care and advice

Standard 4
Consumers receive care and advice, appropriate to their presentation and need, that will facilitate the quality use of Pharmacy Medicines and Pharmacist Only Medicines.

5. Documentation

Standard 5
The pharmacy documents the provision of Pharmacist Only Medicines to ensure continuity of care and enhance optimal health outcomes.

6. Rights and needs of consumers

Standard 6
All staff members respect the rights & needs of all consumers.
13 June, 2005

Mr John Low
Pharmacy Co-ordinator
Pharmacists Board of Queensland
GPO Box 2438
BRISBANE Qld 4001

Dear John

ACCESS TO BOARD DISCIPLINARY INFORMATION

I hereby request permission from the Pharmacists Board of Queensland to access Board disciplinary case information for the purpose of collecting information for my PhD. I enrolled in August 2004 in a PhD at Griffith University with the title “Professional pharmacy practice: Maintaining practice standards in the context of an expanding role” with you as external supervisor. Professor Nerida Smith, the new Head of the School of Pharmacy, has replaced Professor Anne McMurray as my principal supervisor and Dr Kim Forrester is my other supervisor.

My research will cover the extent to which community pharmacy practice reflects pharmacists’ knowledge of the need for risk management and the extent to which...
contemporary practice reflects professional standards as endorsed by the Board. Access to Board cases would provide me with insight regarding the Board’s interpretation and utilization of practice standards and the relevance of various components/sections of the standards.

In support of my request I attach the following documentation:

- Copy of approval to enrol in a PhD.
- Copy of a reference letter from the Registrar of the South African Pharmacy Council, where I worked as an employee for 3 years with access to confidential information.

I have experience in dealing with confidential information and also worked at Pharmaceutical Advisory Services, Queensland Health for approximately 2 years with access to privileged information.

Notes from disciplinary cases should help me in forming an approach towards my research. All information will remain as confidential and will be used to gain an overall perspective of Board processes. Information about businesses or persons will be de-identified and will be stored securely with access only by myself.

Please do not hesitate to contact me if you need any additional information to support my request.

Sincerely

Laetitia Hattingh (MPharm BPharm GCAppLaw AACPA)
Lecturer: School of Pharmacy
APPENDIX 3: CONTRACT WITH THE PHARMACISTS BOARD OF QUEENSLAND.

Confidentiality Agreement

This is an agreement between Ms Letitia Hattingh a PhD candidate at Griffith University and the Pharmacists Board of Queensland.

The Pharmacists Board of Queensland agrees to provide Ms Hattingh with information relating to disciplinary action undertaken by the Board pursuant to the Health Practitioners (Professional Standards) Act 1999. This information is provided to Ms Hattingh for the purpose of collecting information for her PhD which has the title ‘Professional pharmacy practice: Maintaining practice standards in the context of an expanded role’.

The information is provided on the understanding that

- it will remain confidential to Ms Hattingh and her supervisors Professor Narida Smith and Dr Kim Forrester and any other person directly involved in the supervision of her PhD;
- for the purposes of security it will not be accessible on any networked computer at the Griffith University Gold Coast Campus;
- it will only appear in publications directly involved in Ms Hattingh’s PhD studies and will be in a de-identified form unless such information is already publicly available;
- the Board will be reimbursed by Ms Hattingh for any costs associated with the provision of the information;
- the Board will be provided with copies of any publications related to the use of the information so provided.

On behalf of the Board

Ms Hattingh

Signature

Name

Date 11 October 2003

Pharmacists Board of Queensland

[Logo]
## APPENDIX 4: SUMMARY OF DISCIPLINARY CASES.

### Supplied excessive quantities of pseudoephedrine

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Date &amp; type</th>
<th>Type of complaint</th>
<th>Category</th>
<th>Evidence used</th>
<th>Finding(s)</th>
<th>Action recommended</th>
</tr>
</thead>
</table>
| 1 (1) | 014 April 2000 IR | Supplied high quantities of Sudafed – either illegal export or for other purposes | Sale of > pseudoephedrine – probably not negligent but knew what was doing Also illegal export | • Information received from pharmaceutical wholesalers  
• TGA information re regulation of export and issuing of licences & permits  
• Info. from *** Group re export of Sudafed  
• Letter from accused pharmacist  
To quote from Mr ** submission ‘I was advised they had a relative in the pharmaceutical industry in Taiwan and wished to purchase Sudafed for transport to and resale in Taiwan. One was a tour operator providing tours for Taiwanese’ | Supplied multiple packs to individuals at a frequency that was not therapeutically justifiable or was for non-therapeutic purposes. “This constitutes unsatisfactory professional conduct in that it is professional conduct that demonstrates incompetence, or a lack of adequate knowledge, skill, judgement or care, in the practice of the registrant’s profession.” | Referred to the Health Practitioners Tribunal  
Refer Board Bulletin: The tribunal found that the registrant had not acted in accordance with good pharmacy practice. ……..The Tribunal was satisfied the registrant was guilty of unsatisfactory professional conduct in the conduct was of a lesser standard that that which might reasonably be expected of the registrant by the public or the registrants professional peers and that the conduct demonstrated a lack of adequate judgement. |
nationals to Australia. I questioned this person extensively, asking for and being given assurances that the product was for resale in Taiwan, pointing out that I was concerned it may be used for illicit purposes in Australia. They were adamant that the stock was for resale in Taiwan and I was subsequently shown some personal identification. My question in relation to the exit from Australia and entry to Taiwan was met with the reply “I do this all the time with no problems”. A further point of assurance for me was the fact that one of these persons was living in our area and I see him in the pharmacy every now and then…”
<table>
<thead>
<tr>
<th>Tribunal</th>
<th>24 April 2000 BR</th>
<th>Sold 1706 packs of Sudafed 60mg 90's for 1999</th>
<th>Sale of &gt; pseudoephedrine – probably not negligent but knew what was doing</th>
</tr>
</thead>
<tbody>
<tr>
<td>15(2)</td>
<td>24 April 2000 BR</td>
<td>Sold 1706 packs of Sudafed 60mg 90's for 1999</td>
<td>Sale of &gt; pseudoephedrine – probably not negligent but knew what was doing</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Quote the exact text in thesis:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Board bulletin January 1996</td>
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<td></td>
<td></td>
<td></td>
<td>• Board bulletin July 1997</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Board bulletin July 1998</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Pharmaceutical suppliers records – indicating purchases in excess of 10 times the national average</td>
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<td></td>
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<td>• PSA Code of conduct</td>
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<td></td>
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<td></td>
<td>“Having consulted my assessors I have concluded that a pharmacist, entrusted with the responsibility or 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. Sao much is expected by the public and by other members of the profession”</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Registration suspended for 9 months</td>
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<tr>
<td></td>
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<td></td>
<td>Board enter into the following undertakings with the registrant pursuant to section 118(1)(c)(iv) of the Act:</td>
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<tr>
<td></td>
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<td></td>
<td>a) that sales of schedule 2 and schedule 3 drugs be in accordance with the Pharmaceutical Society of Australia Standards for the Provision of Pharmacist Only and Pharmacy Medicines in Community Pharmacy.</td>
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<td></td>
<td>b) that the Guild Quality Care Program accreditation at the Pharmacy be maintained</td>
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<td></td>
<td></td>
<td></td>
<td>c) that registrant maintain</td>
</tr>
<tr>
<td>Date</td>
<td>Tribunal</td>
<td>Charge Description</td>
<td>Evidence</td>
</tr>
<tr>
<td>-------</td>
<td>----------</td>
<td>------------------------------------------------------------------------------------</td>
<td>----------</td>
</tr>
<tr>
<td>25 (3) Dec 2001</td>
<td>Tribunal</td>
<td>Convicted of an indictable offence refer s124(1)(i) – three occasions sold large quantities of Sudafed for manufacture of methylamphetamine</td>
<td>Sale of large quantities of Sudafed</td>
</tr>
<tr>
<td>27 (4) Oct 2003</td>
<td>Tribunal</td>
<td>Convicted in Supreme Court on 4 accounts of producing a dangerous drug</td>
<td>Selling large amounts of Sudafed &amp; iodone</td>
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</tbody>
</table>
his professional standards. So a significant punishment must be imposed in the circumstances."

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Date &amp; type</th>
<th>Type of complaint</th>
<th>Category</th>
<th>Evidence used</th>
<th>Finding (s)</th>
<th>Action recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 (1)</td>
<td>0705 August 2005 DN</td>
<td>The registrant did mistakenly dose the patient with 625 mg instead of 125 mg of methadone as a syrup</td>
<td>Dispensing error (wrong dose)</td>
<td></td>
<td>The reason for the Decision of the Pharmacists Board that a ground for disciplinary action is not established is that although the registrant did mistakenly dose the patient with 625 mg instead of 125 mg of methadone as a syrup, his actions subsequent to the event complied with the accepted procedures to follow in the case of a dispensing error. In addition he went to considerable lengths to find the patient and resolve any problems resulting from the overdose despite receiving incorrect information from the patient himself.</td>
<td>No further action Refer Board Bulletin</td>
</tr>
</tbody>
</table>

Dispensing errors

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Date &amp; type</th>
<th>Type of complaint</th>
<th>Category</th>
<th>Evidence used</th>
<th>Finding (s)</th>
<th>Action recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 (2)</td>
<td>126 January 2001 IR</td>
<td>Wrongly interpreted a prescription for Letrozole 2.5mg and dispensed Ledertrexate to be taken daily</td>
<td>Dispensing error &amp; no counselling &amp; dispense out-of-date stock (wrong product)</td>
<td>Letter of complaint from Medical Oncologist Dispensed bottle of Ledertrexate with 17 tablets Small survey of 9 community pharmacists to read Rx, 6 correct 3 not but said</td>
<td>Wrongly interpreted a prescription for Letrozole 2.5mg and dispensed Ledertrexate. Although expressed reservations about the dose on the prescription to the patient he made no attempt to confirm the drug or the dose with the prescriber. Did not appropriatly counsel the patient nor warn her of possible toxic</td>
<td>Referred to Professional Conduct Review Panel Good case as example – refers to practice standard</td>
</tr>
<tr>
<td>Date</td>
<td>Event</td>
<td>Details</td>
<td></td>
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</tr>
<tr>
<td>Feb 2003</td>
<td>Dispensed Aldazine (thioridazine) instead of Aldactone</td>
<td>Patient experienced debilitating symptoms, phoned pharmacist three times before swapping tablets at home, said she could drive although very drowsy and dizzy, didn’t attempt to contact doctor.</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Feb 2003</td>
<td>Dispensing error (wrong product)</td>
<td>Complainant’s letter – she contacted Board to get advice and contacted pharmacy twice before they exchanged tablets at home.</td>
<td></td>
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</tr>
<tr>
<td>Feb 2003</td>
<td>The most common dispensing error investigated by the Board involves the incorrect selection of the medicine from the shelf when the correct medicine is entered into the computer. The most common reason why such errors form the ground for a complaint against the practitioner is because the pharmacist concerned does not manage the resolution of the error to the satisfaction of the complainant. The complainant is often left 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 recognized or addressed by the pharmacist.</td>
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</tr>
<tr>
<td>Feb 2003</td>
<td>Pharmacy since implemented PDL guide to good dispensing practice and PDL process to follow in case of a dispensing error. On day prescription was dispensed the pharmacist and dispensary assistant dispensed 162 prescriptions. Didn’t notify doctor of error.</td>
<td></td>
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</tr>
</tbody>
</table>

That pursuant to section 118(1)(c)(iii) of the *Health Practitioners (Professional Standards Act) 1999* the Pharmacists Board of Queensland undertake disciplinary proceedings itself on the grounds of unsatisfactory professional conduct in that:

a. in dealing with the dispensing error he demonstrated a lack of adequate knowledge and care; and

b. his professional conduct in responding to repeated requests for information from the investigator regarding the dispensing error was of a lesser standard than that which might reasonably be expected of a registrant.
It is unlikely that workload was an issue in this matter as the workload for the day (162 prescriptions) was approximately 18 prescriptions per hour with a pharmacist and a dispensary assistant on duty in the dispensary. Although there is a lack of research-based data concerning safe or acceptable workload, a figure of 15 prescriptions per pharmacist per hour was accepted some years ago by the Victorian and South Australian Pharmacy Boards as professionally appropriate for pharmacist.

<table>
<thead>
<tr>
<th>Date (10 fu)</th>
<th>Event</th>
<th>Reason</th>
</tr>
</thead>
</table>
| March 2004  | Dispensing error (wrong product) | 1. Dispensed Aldazine instead of Aldactone  
2. Provided patient with advice that she should drive a motor vehicle to her doctor’s surgery while she was under the influence of a drug.  
3. Did not respond to a notice issued pursuant to section 78 of the Health Practitioners (Professional Standards) Act 1999 when he was required to provide information regarding the dispensing of Aldazine to patient |

Under section 165(2)(a) of the Act the Board reprimands for unsatisfactory professional conduct in that (1) his professional conduct was of a lesser standard that which might reasonably be expected of him by the public or his professional peers; and (2) his professional conduct demonstrated a lack of adequate knowledge, skill, judgement or care in the practice of his profession.

Under section 165(3)(a) the Board further determined that the decision to reprimand the registrant
1. A prescription for sodium ascorbate was supplied as calcium ascorbate.

2. A Product Manufacturing Record for Calcium Ascorbate Infusion apparently prepared by ? and dispensed by ?.

3. An incident report and provided to Pharmaceutical Defence Ltd.

4. Written response to interview questions put by ****, Pharmacists Board Investigator

5. Statements made during the disciplinary hearing where it was acknowledged that the full implications of changing the ascorbate from the sodium salt to the calcium salt may not have been properly considered.

Questions:

1. Why only reprimanded registrant if error procedure was so incorrect and registrant didn’t co-operate?

2. Why would not record decision?

Under section 165(2)(a) of the Act the Committee **cautions** for unsatisfactory professional conduct in that (1) his professional conduct was of a lesser standard that which might reasonably be expected of him by the public or his professional peers and (2) is professional conduct demonstrated a lack of adequate knowledge, skill, judgement or care in the practice of his profession.

In cautioning the Committee urges him to ensure any dispensed product supplied to patients in the course of his professional practice is inherently safe; or where

<table>
<thead>
<tr>
<th>12</th>
<th>March 2004</th>
<th>Sodium ascorbate supplied as calcium ascorbate (IV infusion)</th>
<th>Extemporaneous compounding error</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1. A prescription for sodium ascorbate was supplied as calcium ascorbate.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. A Product Manufacturing Record for Calcium Ascorbate Infusion apparently prepared by ? and dispensed by ?.</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>3. An incident report and provided to Pharmaceutical Defence Ltd.</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>4. Written response to interview questions put by ****, Pharmacists Board Investigator</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>5. Statements made during the disciplinary hearing where it was acknowledged that the full implications of changing the ascorbate from the sodium salt to the calcium salt may not have been properly considered.</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>Event</td>
<td>Details</td>
<td>Actions</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Jun 2003 | BR (r 14) (5)  | Incorrectly dispensed MS Contin 10mg as MS Contin 100mg. Patient took 130mg bd instead of 40mg bd and was admitted to hospital - diagnosed with bronchitis and delusions secondary to hypoxia, difficulty in swallowing. During admission dose error was discovered. Dispensing error (wrong strength).  | Medical Centre & ****Hospital medical records  
S87(3)(g) & 88(2) of Health (Drugs and Poisons) Regulation 1996  
Empty MS Contin 100mg box with label  
No barcode scanning  
No adequate staff  
Neither owner nor dispensing pharmacist checked controlled drugs stock balance until received letter from complainant’s solicitor (6 weeks later) – should have given written notice about balance to chief executive.  
Previous Board recommendation to implement barcode scanning technology ignored (3rd complaint in 3 years re serious dispensing error) - lack of effective checking process to detect errors.  
Didn’t apologise to patient afterwards & didn’t contact doctor.  
No incident report.  
Pharmacy very busy & high dispensing workload.  | Undertake disciplinary actions against owner.  
System breakdown as 3 pharmacists were involved with the preparation & supply all assumed the safety of calcium ascorbate had been established. There may be an element of risk the product is accompanied with instructions regarding its safe use including advice in regard to those circumstances in which the product may be dangerous or its use inadvisable.  
Under section 165(3)(a) the Committee further determines that the decision to caution the registrant would not be recorded in the register.  |
<table>
<thead>
<tr>
<th>14 (r 13)</th>
<th>Feb 2004 DN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Had not operated the Pharmacy in accordance with accepted professional standards. Checking of the MS Contin 10 mg and 100 mg strengths, as required by the *Health (Drugs and Poisons) Regulation 1996*, would have revealed an irregularity in the stock totals which would have reasonably lead to the realization that a dispensing error had been made. Made no attempt to apologize for the error or to contact doctor to discuss the matter, in accordance with the Guidelines, *Procedures to Follow in Case of a Dispensing Error*, developed by the Pharmaceutical Defence Ltd and incorporated into the Pharmacy Guild of Australia Quality Care Pharmacy Program. The Board also took issue with attitude to compliance with the accreditation standards of the QCPP and his lack of insight into the requirements of the QCPP’s self-assessment process.

Under section 165(2)(a) of the Act the Board reprimands for unsatisfactory professional conduct in that (1) his professional conduct was of a lesser standard than which might reasonably be expected of him by the public or his professional peers; and (2) his professional conduct demonstrated a lack of adequate knowledge, skill, judgement or care in the practice of his profession.

Under section 165(3)(a) the Board further determined that the decision to reprimand the registrant would not be recorded in the register.

The Board also noted the undertakings to the Board to (1) comply with the *Health (Drugs and Poisons) Regulation 1996* in particular your attention to controlled drugs and the sale of schedule 3 medicines; (2) to comply with the elements of the Pharmacy Guild of Australia Quality Care Pharmacy

244
Ten take-away methadone doses supplied – child died of accidentally taking the methadone – all 10 doses in one bottle with inappropriate labelling and no child proof cap. Unbalanced S8 stock.

Dispensing interval of S8 repeats incorrect (too many take-away doses)

Coroner’s Court inquest into death of child

Procedures outlined in Qld Methadone Program Policy, Procedures & Treatment manual

Health (Drugs and Poisons) Regulation 1996

PSA practice standards re supply of methadone

Previous inspection reports

Supplied ten take away doses of methadone (equivalent to 80 mL of methadone syrup 5 mg/mL) to patient to cover the period 2 June 2000 to 11 June 2000. This supply did not comply with the procedures outlined in the Queensland Methadone Program Policy, Procedures and Treatment Manual, or with sections 62, 82 & 85 of the Health (Drugs and Poisons) Regulation 1996, or with accepted standards of professional practice developed by the Pharmaceutical Society of Australia of which he was and is a member.

From the information provided by Queensland Health, registrant had been subject to least three inspections since 1991. On each occasion discrepancies were found in his controlled drugs register. In an inspection carried out in July 2003 discrepancies were found in seven different controlled drugs. Registrant was unable to offer an explanation in any of those cases. He stated during Refer for hearing by the Health Practitioner Tribunal as the Board believes registrant is guilty of unsatisfactory professional conduct in that his conduct demonstrated a lack of adequate knowledge, skill, judgement and care in the practise of his profession and was of a lesser standard than that which might reasonably be expected by the public or professional peers. The Board seek the following orders from the Tribunal

1. Be suspended from the pharmacists register for a period of 3 years
2. Demonstrate that he is competent to practise before being re-registered by the Board
3. Undertake the Australian College of Pharmacy Program and to undertake at his own cost an annual assessment to ensure the requirements are being met; and (3) to employ an additional full time equivalent pharmacist to his current staff.
In an interview with Environmental Officer that he never undertook audits of his controlled drugs, he just assumed the register was correct. Over a period covering at least 13 years as, at best, shown a cavalier attitude to the management of controlled drugs in his possession.

Practice and Management modules

| Tribunal | • Inadequate record keeping  
• Failure to keep up-to-date regulations |
|----------|----------------------------------------------------------------------------------|

Quote from Tribunal case to start section in thesis

Penalties similar to the ones suggested by Board

<table>
<thead>
<tr>
<th>20 March 2004 BR</th>
<th>Methotrexate tablets only labelled on outer box and patient subsequently took tablets daily</th>
</tr>
</thead>
</table>
| Dispensing error (substandard labelling) | • Unlabelled methotrexate bottle  
• No evidence of CMI  
• No evidence of counselling  
• Copy of patient’s medical records  
• Patient’s medication record: 5 methotrexate injections  
• AMH 2004 regarding MTX labelling  
• APF 19th ed. re labelling  
• APF 19th ed. re counselling criteria  
• Board bulletin 19 “The criteria for |

Interview with rheumatologist: surprised that patient didn’t know should be weekly as she few years ago used tablets. My question: why no contributory negligence? – refer article no Code of Health Rights & Responsibilities

In this matter where treatment with methotrexate tablets was initiated, the pharmacist had a duty of care to ensure the patient was clear in her understanding on the use of the medicine. This could have been best achieved by ensuring the primary container was clearly labelled with directions for use (including ancillary labels) and the patient (or carer) was counselled about the methotrexate with such

Pursuant to section 118(1)(c)(iii) the Board deals with the disciplinary matter by taking disciplinary proceedings itself.
The patient in this case was prescribed methotrexate tablets weekly, but started taking them daily. It is probable that the patient would have taken the methotrexate tablets weekly as prescribed, rather than daily, if they had received proper counselling and had a CMI.

While it is unfortunate that the patient did not contact the rheumatologist or the pharmacist to confirm the dose in the absence of any written instructions before she began taking the methotrexate tablets on a daily basis, there would appear to be a failure in the duty of care owed to her by the pharmacist.

<table>
<thead>
<tr>
<th>Board</th>
<th>Relevant codes of practice and relevant literature</th>
<th>Registrant is to be cautioned</th>
<th>Disciplinary action not be recorded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug 2005 DN</td>
<td>Owner didn't ensure that manager complied with HDPR regarding S8 register</td>
<td>Manager didn't comply with HDPR (record keeping)</td>
<td>Reports provided by Drugs of Dependence Unit</td>
</tr>
<tr>
<td>June 2006</td>
<td>Illegal substitution</td>
<td>Dispensing error (substitution)</td>
<td>Board policy on generic substitution</td>
</tr>
<tr>
<td>No.</td>
<td>Date</td>
<td>Description</td>
<td>PBS</td>
</tr>
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</tr>
<tr>
<td>30</td>
<td>May 2006-10-09</td>
<td>Notice &amp; DN</td>
<td>PBS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dispensed Carafate instead of Caltrate</td>
<td>Dispensing error (wrong product) Carafate bottle protocols that stated that enquiries re generic medication were to be handled by the pharmacist on duty</td>
</tr>
<tr>
<td>31</td>
<td>Nov 2005</td>
<td>Dispensed Dothep 75mg instead of Dothep 25mg, wrong doctor on label</td>
<td>Dispensing error (wrong strength)</td>
</tr>
<tr>
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</tr>
<tr>
<td>32</td>
<td>Dec 2005 DN</td>
<td>S8 balance discrepancies &amp; s8's not stored in approved receptable</td>
<td>Dispensing error – s8 records and storage (record keeping)</td>
</tr>
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<td></td>
<td></td>
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</tr>
<tr>
<td>33</td>
<td>Feb 2006</td>
<td>S8 balance discrepancies &amp; s8's not stored in approved receptable</td>
<td>Dispensing error – s8 records and storage (record keeping)</td>
</tr>
<tr>
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<tr>
<td>No.</td>
<td>Date</td>
<td>Description</td>
<td>Action</td>
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</tr>
<tr>
<td>35</td>
<td>? 2006</td>
<td>Dispensed wrong strength methotrexate and didn’t counsel or provide written instructions</td>
<td>Dispensing error (wrong strength)</td>
</tr>
<tr>
<td>36</td>
<td>May 2006</td>
<td>Discrepancies S8 register</td>
<td></td>
</tr>
<tr>
<td>37</td>
<td>May 2006</td>
<td>Made a range of dispensing errors</td>
<td>Dispensing errors (wrong product, labelling errors)</td>
</tr>
<tr>
<td>39</td>
<td>2006 DN</td>
<td>Made a range of dispensing errors</td>
<td>Dispensing errors (no dosage instruction on label, no counselling) Unlabelled box of Tramal PSA competency standards for pharmacists PSA CMI guidelines</td>
</tr>
</tbody>
</table>
### Inappropriate S3 supply

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Date &amp; type</th>
<th>Type of complaint</th>
<th>Category</th>
<th>Evidence used</th>
<th>Finding(s)</th>
<th>Action recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>34</td>
<td>Aug 2006 DN</td>
<td>No questioning about therapeutic need, age, BMI &amp; no counselling</td>
<td>OTC counselling</td>
<td>PSA Xenical (orlistat) supply protocol</td>
<td>Inappropriately supply S3 to 15 year old without adequately assessing her</td>
<td>Registrant cautioned to follow correct protocol, undertaking to complete the PSA CPE weight management module Not recorded</td>
</tr>
<tr>
<td>41</td>
<td>Aug 2006</td>
<td>No questioning about therapeutic need, no counselling</td>
<td>OTC counselling</td>
<td>S277 of H(D&amp;P) Reg 1996</td>
<td>Supply of Mersyndol &amp; Canesten ? whether pharmacist asked correct questions</td>
<td>Ground for disciplinary action not established</td>
</tr>
</tbody>
</table>

### Inappropriate owner supervision

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Date &amp; type</th>
<th>Type of complaint</th>
<th>Category</th>
<th>Evidence used</th>
<th>Finding(s)</th>
<th>Action recommended</th>
</tr>
</thead>
</table>
| 19   | May 2002 BR | Pharmacy owner failed to appropriately supervise manager who, without Rx’s, sold large quantities of ephedrine, anabolic and androgenic steroids, human chorionic gonadotrophin and also | Inappropriate owner supervision & procedures – manager fraud | • Faulding tax invoice  
• Purchasing records from wholesalers  
• Info. from HIC re PBS claims  
• Rx’s for anabolic & androgenic steroids etc.  
• Manager’s declaration that owner had no knowledge of his | Evidence that the following quantities of prescription medicines could not be accounted for through the dispensing records for the period 1 January 2001 to 31 December 2003:  
340 x Ephedrine HCl tablets 30 mg 100  
371 x Profasi HCG 500 units  
81 x Proviron tablets 25 mg 50  
465 x Primoteston Depot 250 mg 3  
244 x Primobolan tablets 5 mg 50  
31 x Deca Durabolin 50 mg/mL  
465 x Deca Durabolin 50 mg/mL 1 mL x 3 | Pursuant to section 118(1)(c)(iii) of the Health Practitioners (Professional Standards Act) 1999 the Board undertake disciplinary proceedings itself against owner on the grounds of unsatisfactory professional conduct in that:  
a) there was a failure by her as the owner of the pharmacy to apply an appropriate level of supervision to satisfy herself that the pharmacy was being operated to a professional |
<p>| | | |</p>
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<tbody>
<tr>
<td><strong>pseudoephedrine</strong>&lt;br&gt;Manager under investigation by Qld Police Service</td>
<td>activities</td>
<td>In addition the following quantities of pseudoephedrine-containing products were purchased for the period 1 January 2002 to 31 December 2003: 938 x Telfast Decongestant 10 360 x Logicon Sinus 30 140 x Sudafed 12 hr Caplet 1520 x Sudafed Sinus and Nasal Although an investigation into the activities is proceeding, there is no evidence that owner had any involvement in or knowledge of these matters. Manager has signed a statement to that effect. There is evidence that computer generated orders were altered after the stock was received to conceal the fact that large quantities of some restricted drugs were being purchased. It was normal process for the manager to check off the invoices against the monthly statement and forward the statement to owner for payment.</td>
</tr>
<tr>
<td>23 (2)</td>
<td>Oct 2003</td>
<td>Tribunal</td>
</tr>
<tr>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Failed to properly supervise staff  
Inappropriate handing over of power to non-pharmacists  
Offences against HDPR  
Offences against Health Act 1953  
Dispensing of Rxs while absent from pharmacy  
Refer to health Practitioner Tribunal

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Date &amp; type</th>
<th>Type of complaint</th>
<th>Category</th>
<th>Evidence used</th>
<th>Finding (s)</th>
<th>Action recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 (1)</td>
<td>123 October 2000 IR</td>
<td>The use of medical drug samples in the dispensing of pharmaceutical benefit prescriptions</td>
<td>Fraud: Dispensing &amp; claiming drug samples</td>
<td>Complainant supplied 2 dispensed packs</td>
<td>Evidence indicated twice dispensed of samples and once claimed HIC benefit</td>
<td>The Board enter into an undertaking with the registrant that the registrant will not use medical sample packs of drugs when dispensing prescriptions</td>
</tr>
</tbody>
</table>
| 9 (2) | 210 Oct 2003 | The Board received information from the Health Insurance Commission that they had commenced an investigation in 1999 in relation to fraudulent claiming from the HIC under the HIC fraud | | | | Pursuant to section 118(1)(c)(i) the Board refers the disciplinary matter for hearing by the Health Practitioner Tribunal  
The Board seeks the following orders from the Tribunal:  
1. suspended from the pharmacists register for a period of 4 years;  
2. demonstrate that he is competent to practise |
<table>
<thead>
<tr>
<th>No.</th>
<th>Date</th>
<th>Name</th>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>Aug 2004</td>
<td>BR</td>
<td>Made false prescriptions entries for tax purposes</td>
<td>Fraud: Prescription copies for Xenical and Vioxx – private claims (not HIC fraud) and there is no evidence that the medicines involved were removed from the pharmacy. Registrant has been found guilty in Magistrate’s Court of falsifying a document or record, a significant offence for a pharmacist. Obligation 2.2 of the Code of Professional Conduct recently adopted by the Board states: A pharmacist must act with honesty and integrity, having due regard for standards of behaviour accepted within the profession and reasonably expected by the community and other health professions. That pursuant to section 118(1)(c)(iii) of the Health Practitioners (Professional Standards Act) 1999 the Board undertake disciplinary proceedings itself against registrant on the grounds of unsatisfactory professional conduct in that she made false prescription entries for both herself and her husband at the Pharmacy with the intention of producing a fraudulent taxation history report.</td>
</tr>
<tr>
<td>17</td>
<td>Oct 2004</td>
<td>DN</td>
<td></td>
<td>Under section 165 (2) (a) of the Act the Board cautions registrant for unsatisfactory professional conduct in that her behaviour was fraudulent or dishonest in the practice of her</td>
</tr>
<tr>
<td>No.</td>
<td>Date</td>
<td>Authority</td>
<td>Offence Description</td>
<td>Event</td>
</tr>
<tr>
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<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>21</td>
<td>March 2004</td>
<td>IR</td>
<td>Stole money from pharmacy &amp; dispensed S8s before had Rx &amp; Discrepancies in S8 register</td>
<td>Found guilty in Townsville District Court stealing money from pharmacy - Registrant has been convicted of indictable offence On 5 occasions dispensed S8’s before having the Rx &amp; behaved in a way that constitutes unsatisfactory conduct &amp; was reckless in his management of S8s Refer for disciplinary hearing by Health Practitioners Tribunal</td>
</tr>
<tr>
<td>26</td>
<td>Nov 2001</td>
<td>Tribunal</td>
<td>Convicted of an indictable offence – 48 offences of defrauding the HIC</td>
<td>“It is to be also kept in mind that the jurisdiction exercised by the Tribunal is not essentially punitive, although that may some times be the effect of the Tribunal’s orders. This does not however mean that the issue of deterrence is of no relevance, for one of the matters which the Tribunal must consider is the effect which any order will have upon other practitioners who might be minded to act in ways similar to the present Registrar.”……. “It is trite to say that professional behaviour implies honest.” “The profession and the public are Registration cancelled for 3 year Not own pharmacy For one year work under supervision of another pharmacist</td>
</tr>
</tbody>
</table>
entitled to expect that those involved in the provision of health services will demonstrate the highest levels of probity (eerlikheid) in dealing with those agencies which, in one way or another, provide funding for such services."

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<tbody>
<tr>
<td>38</td>
<td>Nov 2004</td>
<td>Tribunal</td>
<td>Convicted of an indictable offence - HIC Fraud</td>
<td>Fraud</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Not much information, this was a follow-up from a civil court decision</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Registration cancelled etc.</td>
</tr>
</tbody>
</table>

38 (6) | Nov 2004 Tribunal | Convicted of an indictable offence - HIC Fraud | Fraud | Not much information, this was a follow-up from a civil court decision | Registration cancelled etc. |

40 (7) | Sep 2006 DN | Took medicines form pharmacy & Medicare fraud | Fraud | Discrepancies in pharmacy records Dispensed histories | Between July 2002 and May 2003 registrant was in possession of restricted medicines namely Codeine linctus and Panadeine Fort without prescriptions During September 2001 and December 2002 registrant generated false prescriptions | Reprimanded & undertakings (blocked out due to privacy reasons), not recorded | Referred for health assessment (codeine abuse) |

### Illegal export

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Date &amp; type</th>
<th>Type of complaint</th>
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<th>Evidence used</th>
<th>Finding (s)</th>
<th>Action recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 (cont 6) (1)</td>
<td>136 May 2001 BR</td>
<td>Convicted in the Cairn’s Magistrates Court of 54 offences against the Therapeutic Goods Act 1989, of exports of therapeutic goods from Australia. The illegal export of medicines, including S8</td>
<td>The Pharmaceutical Society of Australia Code of Professional Conduct states at Principle Two that: ‘A pharmacist must at all times uphold the reputation of the professional’</td>
<td>Board to follow-up with disciplinary proceedings Good reference to definition of unsatisfactory professional conduct and Code of Professional Conduct: Unsatisfactory professional conduct may include: professional conduct that is of a lesser standard than that which might reasonably be expected</td>
<td></td>
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<tr>
<td>Conviction was recorded and Investments fined $30,000</td>
<td>and adhere to the legislation applicable to the practice of pharmacy.’ The first obligation under Principle Two states ‘A pharmacist must act according to the laws and regulations concerning the profession and adhere to the Code of Professional Conduct.’</td>
<td>by the public or the registrant’s professional peers; professional conduct that demonstrates incompetence, or a lack of adequate knowledge, skill, judgement or care in the practice of the registrant’s profession; or, conduct discreditable to a registrant’s profession.</td>
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</tr>
<tr>
<td>6 (5 fup)</td>
<td>136 May 2003 DN</td>
<td>Illegal export of medicines, including S8</td>
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</tr>
<tr>
<td>Unsatisfactory professional conduct in that (1) his professional conduct was of a lesser standard than that which might be expected of him by the public or his professional peers; and (2) his professional conduct demonstrated a lack of adequate knowledge, skill, judgement or care in the practice of his profession.</td>
<td>Under section 165(3)(a) the Board further determined that the decision to caution the Registrant would not be recorded in the register. The Board also noted the undertaking of the Registrant to the Board to undertake and successfully complete within 12 months the Pharmacy Guild of Australia - Quality Care Pharmacy Program (or a similar program approved by the Board) for his pharmacy in Cairns, paying particular attention to professional and regulatory</td>
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</table>
requirements of the Program, and to report to the Board on its completion.

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<tr>
<th>Reference</th>
<th>Date &amp; Type</th>
<th>Type of complaint</th>
<th>Category</th>
<th>Evidence used</th>
<th>Finding(s)</th>
<th>Action recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>22 (2)</td>
<td>July 2004 BR</td>
<td>Dispensed prescriptions for patients residing in USA</td>
<td>Illegal export – prescriptions written overseas and therefore not valid</td>
<td>Board taking disciplinary proceedings itself</td>
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</table>

Practised without registration

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<tr>
<th>Ref.</th>
<th>Date &amp; Type</th>
<th>Type of complaint</th>
<th>Category</th>
<th>Evidence used</th>
<th>Finding(s)</th>
<th>Action recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 (cont 8) (1)</td>
<td>146 Feb 2001 IR</td>
<td>Worked as a locum pharmacist at a number of **** pharmacies while unregistered. He claims to have been under the mistaken impression that registration was for 3 or 5 years although he has given the investigator no idea as to how that impression was gained</td>
<td>Practised without registration</td>
<td>Board to follow-up with disciplinary proceedings Board write to pharmacists that employed him emphasising importance of ensuring employees’ registration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8 (7 fu)</td>
<td>146 Nov 2001</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td>---</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Under section 165(2)(a) of the Act, the Board reprimands the Registrant in that his professional conduct demonstrated a lack of adequate care in the practice of pharmacy. Under section 165(3)(a) the Board further determined that the decision to reprimand the Registrant would not be recorded in the register</td>
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</table>
APPENDIX 5: SEMI-STRUCTURED INTERVIEW QUESTIONNAIRE.

Laetitia Hattingh PhD research

Questions for semi-structured interview

Thank you for taking the time to see me today.

I have a series of questions to help guide the interview. There are no wrong answers to these questions, so please feel free to share your point of view and experience. The interview will be tape-recorded to help me remember all of your comments. At this point can I just check if you are happy for the interview to be tape-recorded? (Turn on recorder and say something like “is the tape-recorder close enough?)

I would like to remind you that everything that is said will remain confidential. Your name will not appear in any reports or publications resulting from this work.

Please give me some information about yourself: where you trained, how many years since you qualified, your career history, do you have any post-graduate qualifications

1. How long have you owned/worked in this pharmacy?

2. Could you describe the professional services provided by the pharmacy? Eg. Smoking cessation, weight management, baby care, medication management reviews, nursing homes, blood pressure monitoring, blood glucose monitoring

3. How many people work in the pharmacy and what are their different roles?
4. Could you describe which of the pharmacy staff are involved in the counselling of patients for over-the-counter medication?
   Pharmacists
   Pharmacy assistants
   Front shop assistants
   Regarding the non-pharmacists, what training have they had?

5. Could you describe to me the process and protocol for the counselling of over-the-counter products?
   Tools
   Record keeping – check dispensed history?
   When to involve a pharmacist

6. Which staff is involved with the dispensing of prescriptions and who does what?
   Pharmacists
   Pre-registration pharmacist
   Dispensing technician

7. How do you decide which patients should be counselled on their prescription medication?

8. Do you have a protocol for issuing a CMI or other counselling tools?
   Which patients
   Which medication
   Do you print it out
   Record keeping of what issued

9. What is the process followed when you or another pharmacist receive a prescription for a medication that in your view does not follow best practice or good clinical evidence?
   Wrong medicine, wrong dose, patient needs additional therapy

10. How are drug interactions identified?
    Computer program eg. Winifred
Pharmacists’ expertise
List of common interactions in pharmacy

11. What is the process in the case of identifying an interaction?
   Drug-drug, drug-disease

12. Which adverse effects do you/the staff counsel patients on (how do you decide which ones are important)?

13. Do you have a system in place to report adverse drug reactions to the Australian Adverse Drug Reactions Advisory Committee?

14. Does the pharmacy have a process in the case of a near-miss error?
   Recording
   Use as education tool
   Notify other pharmacists

15. Could you explain to me the process followed by the pharmacy in the case of an actual error?
   Recording
   Use as education tool
   Notify other pharmacists

16. Can you explain to me processes followed to minimise errors.
   Development
   Implementation
   Review

17. How would you/have you dealt with a staff member who makes a mistake?

18. Many people view pharmacists who make mistakes as being ‘bad’ pharmacists. What is your opinion on this?
19. Could you explain to me whether the pharmacy has any system in place to manage potential medication selection problems for example similar labelling, similar packaging, separating out hypoglycaemics/cytotoxics (eg. methotrexate)?
   Separate on shelve
   Notify staff
   Use colour codes
   Notify manufacturer or professional organisation

20. Do you have protocols and risk management procedures in place?

21. How familiar are you with the professional practice standards?
   Do follow-up question if appropriate (eg. how often work through standards)

22. Do you utilise the professional practice standards (to design processes and protocols)?
   If not, what do you use to design processes and protocols and risk management procedures?

23. How familiar are you with the contents of the QCPP and to what extent do you utilise the QCPP?

24. How familiar are you with the Pharmacists Board of Queensland Policies and guidelines and bulletins?
   Do follow-up question if necessary (eg. how often log onto website)

25. Do you have a process to assess future employees who are from a non-English speaking background (or English not first language)?
   What is your experience with them.
26. Please highlight the good points about your system.

Please highlight the disadvantages about your system or things that you would like to improve.

27. What barriers are there in your pharmacy to following good practice?
   Financial
   Time

28. Where do you go for risk management advice?

Is there anything else what you would like to explain or expand on?

**General prompts** (to be used throughout)
Can you give me an example?
Can you expand on that further?
Is there anything else?
What experiences have you had that make you feel that way?
Dear pharmacist manager,

My name is Laetitia Hattingh and I am a pharmacist enrolled in a PhD through Griffith University. I am interested in the professional responsibility and potential legal liability of pharmacists, specifically in the context of the evolving role of the pharmacist towards patient care services. Australia has been at the forefront of an international trend towards the incorporation of patient care services in community pharmacy practice and I aim to use my research to assist the profession in developing risk management procedures.

Part of my research will involve interviews with a representative sample of pharmacists on the Gold Coast. I am seeking, through your response to the attached expression of interest form, to determine your willingness to be interviewed at your pharmacy. The interview will take approximately one hour and those pharmacists who are interviewed will each receive a Pharmaceutical Society of Australia book voucher worth $50.00, as a small token of appreciation.

Your participation in this study is absolutely voluntary and I understand that you are busy but would really appreciate your time in completing and faxing the form.

If you have any questions about my research please contact me and I will be happy to provide you with more information.

Yours sincerely,

Laetitia Hattingh MPharm BPharm GCAppLaw AACPA

30 June 2006
I hereby give permission for my name to be added to a database of pharmacists that will be used to randomly select a representative sample of pharmacists that will be interviewed.

NAME: ____________________________

GENDER: MALE □ FEMALE □ PLEASE INDICATE YOUR AGE: ________ years

PLEASE INDICATE YOUR QUALIFICATION(S):
BPharm □ Ph.C □ MPharm □ AACPA □ OTHER: __________________________

THE NUMBER OF YEARS OF PHARMACY PRACTICE EXPERIENCE:
< 5 years □ 6 – 10 years □ 11 -15 years □ 16 – 20 years □ > 20 years □

LIST THE PROFESSIONAL ORGANISATIONS YOU ARE A MEMBER OF:

PHARMACY NAME: __________________________

YOUR POSITION AT THE PHARMACY:

ON AVERAGE, HOW MANY DAYS PER WEEK DO YOU WORK IN THE PHARMACY?
4 days □ 5 days □ 6 days □ 7 days □

Privacy statement
The conduct of this research involves the collection, access and/or use of your identified personal information. The information collected is confidential and will not be disclosed to third parties without your consent, except to meet government, legal or other regulatory authority requirements. A de-identified copy of this data may be used for other research purposes. However, your anonymity will at all times be safeguarded. For further information consult the University’s privacy Plan at www.griffith.edu.au/ua/aa/vc/pp or telephone (07) 3875 5585.
APPENDIX 7: INFORMATION PACK FOR INTERVIEW PARTICIPANTS.

INFORMATION SHEET

Project Title:

An investigation of risk management procedures implemented by community pharmacists in the context of an expanding role.

Chief Investigators:

Professor Nerida Smith
Head, School of Pharmacy, Griffith Health
Contact Phone: (07) 5552 9743
Contact Email: Nerida.Smith@griffith.edu.au

Professor Judy Searle
Foundation Dean & Head, of School of Medicine, Griffith Health
Contact Phone: (07) 5678 0702
Contact Email: Judy.Searle@griffith.edu.au

Dr Michelle King
Senior Lecturer, School of Pharmacy
Griffith Health
Contact Phone: (07) 5552 7724
Contact Email: michelle-a.king@griffith.edu.au

Dr Kim Forrester
Jacaranda Chambers, Queen Street, Brisbane
Contact Phone: (07) 3868 2448
Contact Email: kim.forrester@forresterhealthlaw.com.au

Doctoral Student:

Laetitia Hattingh BPharm MPharm GCAppLaw AACPA
Lecturer, School of Pharmacy
Griffith Health
Contact Phone: (07) 5552 7097
Contact Email: L.Hattingh@griffith.edu.au

Laetitia Hattingh is undertaking this research study in meeting the requirements of a PhD. The purpose of the study is to gain an understanding of the practice of pharmacy and the application of practice standards in everyday practice to minimise risk. The study seeks to determine pharmacists’ potential legal liability in the context of the evolving role of the pharmacist towards patient care services as well as the traditional medication supply function. The aim is to use the findings to influence practice behaviour and improve risk management procedures.

The gathering of data for this exploratory study will take place over two phases, namely:

1. An examination of Pharmacists board of Queensland disciplinary files; and
2. Interviews with pharmacists and key stakeholders.
Your participation in the study

Thank you for indicating your willingness on the expression of interest form to be contacted to participate in an interview. Phase 2 of the data gathering process will involve interviews with a representative sample of Gold Coast pharmacists and you've been selected for a semi-structured interview. However, your participation in this study is totally voluntary.

The purpose of the interview is to gather information about the utilisation of professional practice standards and to examine pharmacists’ knowledge of risk management procedures. It is estimated that an interview will take between 30 – 60 minutes and I will organise the interview at a time that is convenient to you.

To obtain maximum benefit from the interview, I will tape-record the interview. The information obtained during your interview will only be available and accessible to the University supervisors and myself and all information will be de-identified in reports and publications. I will provide you with a summary of the findings once the research is completed.

Please contact me if you have any questions about my research and I will be happy to provide you with more detail.

If you have any concerns or complaints concerning the manner in which the research study is conducted it may be communicated to the University’s Research Ethics Manager, Office for Research, Bray Centre, Nathan Campus (Ph 3875 5585).

Thank you for your assistance with this research project.

Laetitia Hattingh

28 July 2006
EXPRESSION OF CONSENT

Project Title:

An investigation of risk management procedures implemented by community pharmacists in the context of an expanding role.

By signing below, I confirm that I have read and understood the information package and in particular have noted that:

- I understand that my involvement in this research will include a semi-structured interview that will be tape-recorded and that the recording will be erased following transcription & analysis;
- I have had any questions answered to my satisfaction;
- I understand that there will be no direct benefit to me from my participation in this research;
- I understand that my participation in this research is voluntary;
- I understand that if I have any additional questions I can contact the research team;
- I understand that I am free to withdraw at any time, without comment or penalty;
- I understand that I can contact the Manager, Research Ethics, at Griffith University Human Research Ethics Committee on 3875 5585 (or research-ethics@griffith.edu.au) if I have any concerns about the ethical conduct of the project; and
- I understand the risks involved;
- I agree to participate in the project.

Name: ____________________________________________________________

Signature: _________________________________________________________

Date: _____________________________________________________________

Privacy statement

The conduct of this research involves the collection, access and/or use of your identified personal information. The information collected is confidential and will not be disclosed to third parties without your consent, except to meet government, legal or other regulatory authority requirements. A de-identified copy of this data may be used for other research purposes. However, your anonymity will at all times be safeguarded. For further information consult the University’s privacy Plan at www.griffith.edu.au/ua/aa/vc/pp or telephone (07) 3875 5585.
APPENDIX 8: PHARMACY REGISTERING AUTHORITIES QUESTIONNAIRE.

<table>
<thead>
<tr>
<th>Professional Misconduct</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Please list the legislation specifying the Board’s investigative and disciplinary processes.</td>
</tr>
<tr>
<td>Briefly describe the disciplinary process.</td>
</tr>
<tr>
<td>2. Please explain to what extent and at what stage the outcomes of disciplinary cases are available to registrants.</td>
</tr>
<tr>
<td>3. Please explain to what extent the outcomes of disciplinary cases are available to the general public.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Processes and Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Has the Board endorsed the Pharmaceutical Society of Australia’s Code of Professional Conduct?</td>
</tr>
<tr>
<td>If yes please expand.</td>
</tr>
<tr>
<td>5. Has the Board endorsed the Pharmaceutical Society of Australia’s Professional Practice Standards?</td>
</tr>
<tr>
<td>If yes please expand.</td>
</tr>
<tr>
<td>6. Has the Board endorsed the Pharmaceutical Society of Australia’s S2/S3 Standards?</td>
</tr>
<tr>
<td>If yes please expand.</td>
</tr>
<tr>
<td>7. Has the Board endorsed the Quality Care Pharmacy Program?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>8.</th>
<th>Does the Board have Board specific practice policies, procedures and guidelines.</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes please provide detailed information.</td>
<td></td>
</tr>
</tbody>
</table>

| 9. | Briefly explain the Board’s role in the **setting** of practice standards. |

| 10. | Please indicate the Board’s policy regarding dispensing bar code scanners eg. whether the Board recommends that pharmacists should use scanners or whether it is a mandatory requirement. This question is separate to the reference to scanners in the QCPP and specifically refers to Board policy. |

### Registrants

| 11. | Please indicate the Board’s policy regarding individual pharmacists & professional indemnity insurance eg. whether the Board recommends that employee pharmacists should have insurance or whether it is a mandatory requirement. This question is separate to the reference to insurance in the QCPP and specifically refers to Board policy. |

| 12. | Please provide information about the Board’s **current** annual re-registration requirements for pharmacists. |

<table>
<thead>
<tr>
<th>13.</th>
<th>Is the Board in the process of developing requirements regarding annual re-registration that would require proof of continuous professional development?</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes please expand and include details regarding the information that</td>
<td></td>
</tr>
</tbody>
</table>
would need to be provided by pharmacists.

14. Is it a requirement of annual re-registration to have a current first-aid certificate?

15. Please provide information about the Board’s pre-registration requirements under the following headings:

<table>
<thead>
<tr>
<th>Required period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescribed program(s)</td>
</tr>
<tr>
<td>Approved/accredited program providers</td>
</tr>
<tr>
<td>Assessments (eg. written, oral/OSCE, APCAT)</td>
</tr>
<tr>
<td>Who conducts the final assessment (eg. provider or Board)</td>
</tr>
</tbody>
</table>

16. Does the Board keep a register of:

<table>
<thead>
<tr>
<th>Pre-registration pharmacists:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy students on placement:</td>
</tr>
</tbody>
</table>

17. Please provide information about registrants’ English skills requirements.

18. Does the Board keep a register of pharmacy support personnel?

| If yes please expand. |

19. Does the Board follow a pharmacy inspection schedule?

| If yes, please expand on: |
• The process and procedure and
• Aspects covered during the inspections.

20. Please provide information about the requirements for pharmacy premises, equipment and resources. Separate between compulsory requirements and recommended requirements.

21. Please provide information on any other premises requirements.

22. Does the Board keep a register of pharmacy premises?
   If yes please expand.

- END OF QUESTIONNAIRE -

THANK YOU FOR YOUR PARTICIPATION

Please send completed questionnaire to:
Laetitia Hattingh
E-mail l.hattingh@griffith.edu.au or
Fax (07) 5552 8804
APPENDIX 9: COUNCIL OF PHARMACY REGISTERING AUTHORITIES (COPRA) E-MAIL TO PHARMACY REGISTERING AUTHORITIES.

Dear Registrar

I am forwarding a questionnaire on request from Laetitia Hattingh from the Griffith University School of Pharmacy. The message immediately below from Laetitia sets out the purpose of the questionnaire.

Dear Pharmacy Board representative

My name is Laetitia Hattingh and I am a PhD student and lecturer at Griffith University. My PhD involves exploring pharmacists’ potential legal liability in the context of an expanding role.

I understand that you are busy but would really appreciate it if you could spend some time in completing the attached questionnaire.

Part of my research involves a comparison of the legal requirements applicable to community pharmacy in the various states and territories. I therefore developed the questionnaire to help me gather information about the requirements that fall within the scope of Pharmacy Regulatory Authorities.

Please complete the questionnaire, either electronically or in hard copy, and return to me by mid-October. Any additional relevant documentation, such as Board policies and procedures, would also be of great assistance.

I will contact you in approx. 4 weeks to discuss the questionnaire and clarify any issues. In the meantime, please do not hesitate to contact me if you have any questions.

Thank you for your assistance with this research project.

Laetitia Hattingh (MPharm BPharm GCAppLaw AACPA)
Lecturer
Griffith Health, School of Pharmacy
Gold Coast campus, Griffith University
G16 R 3.21
PMB 50 Gold Coast Mail Centre, Queensland 9726
Email: l.hattingh@griffith.edu.au
Ph: +61 7 5552 7097
Fax: +61 7 5552 8804

PhD supervisors:

Professor Nerida Smith, Head, School of Pharmacy, Griffith Health
Professor Judy Searle, Foundation Dean & Head, School of Medicine, Griffith Health
Dr Kim Forrester, Jacaranda Chambers, Queen Street, Brisbane
Dr Michelle King, Senior Lecturer, School of Pharmacy, Griffith Health

Laetitia and her supervisors have agreed that COPRA member authorities should be able to share their questionnaire returns for COPRA discussion purposes. I am of the view that, in this way, you will be able to assist pharmacy research and assist ourselves through assembly of an up-to-date set of comparative data on issues which we have addressed in an ad hoc fashion in COPRA over the past few years. To facilitate this, I would be grateful if you could cc your return to me.
Your help will be much appreciated

Regards
Guy

Guy Kretschmer
Executive Officer
Council of Pharmacy Registering Authorities Inc

ph  02 6262 9628
fax  02 6247 5748
mob  0416 089 628

PO Box 269
CIVIC SQUARE  ACT  2608

Web:  www.copra.org.au
APPENDIX 10: SUMMARY OF JURISDICTIONAL REGULATORY REQUIREMENTS.

Participating: all eight pharmacy registering authorities in Australian states and Territories:

- Pharmacists Board of Queensland
- Pharmacy Board of New South Wales
- Australian Capital Territory Pharmacy Board
- Pharmacy Board of Victoria
- Pharmacy Board of South Australia
- Pharmaceutical Council of Western Australia
- Pharmacy Board of Tasmania
- Pharmacy Board of the Northern Territory

Pharmacy registering authorities – Board/Council membership

<table>
<thead>
<tr>
<th>Authority</th>
<th>Membership</th>
</tr>
</thead>
</table>
| Pharmacists Board of Queensland              | At least 7 and not more than 11 members  
  - *Majority* of members must be general registrants nominated by professional organisations and university and one appointed by Minister  
  - Chairperson and Deputy Chairperson appointed by Minister |
| Pharmacy Board of New South Wales            | 9 members  
  - 5 must be pharmacists elected  
  - 3 others appointed by Governor |
| Pharmacy Board of Victoria                   | 12 members – nominated by Minister and appointed by Governor in Council  
  - 6 must be pharmacists |
| Pharmacy Board of South Australia            | 8 members appointed by the Governor  
  - 6 are pharmacists, of which 5 nominated by professional organisations and university  
  - chairperson must be pharmacist |
| Pharmacy Board of Tasmania                   | 7 members nominated by Minister and appointed by the Governor  
  - 5 pharmacists  
  - 2 others |
| Pharmaceutical Council of Western Australia  | 7 elected pharmacists |
| Australian Capital Territory Pharmacy Board  | Members are elected or appointed – on 17 January 2007 7 pharmacists plus 1 community rep  
  2 community representatives |
| Pharmacy Board of the Northern Territory     | Not certain – check website  
  - pharmacists  
  - 2 consumer representatives |

Summary of pharmacy registering authorities’ primary legislation.

<table>
<thead>
<tr>
<th>State/Territory</th>
<th>Legislation</th>
<th>Regulatory Authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Queensland</td>
<td><em>Pharmacists Registration Act 2001 (Qld)</em></td>
<td>Pharmacists Board of Queensland</td>
</tr>
<tr>
<td>New South Wales</td>
<td><em>Pharmacy Act 1964 (NSW)</em></td>
<td>Pharmacy Board of New South Wales</td>
</tr>
<tr>
<td>Victoria</td>
<td><em>Pharmacy Practice Act 2004 (Vic)</em></td>
<td>Pharmacy Board of Victoria</td>
</tr>
</tbody>
</table>
Please list the legislation specifying the Board’s investigative and disciplinary processes.

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th>Legislation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists Board of Queensland</td>
<td>Health Practitioner (Professional Standards) Act 1999 (Qld)</td>
</tr>
<tr>
<td>Pharmacy Board of New South Wales</td>
<td>Pharmacy Act 1964 (NSW) Pharmacy Practice Act 2006 (NSW) to commence in 2007</td>
</tr>
<tr>
<td>Pharmacy Board of Victoria</td>
<td>Pharmacy Practice Act 2004 (Vic) Health Professions Registration Act 2005 (Vic) to commence 1 July 2007</td>
</tr>
<tr>
<td>Pharmacy Board of South Australia</td>
<td>Pharmacists Act 1991 (SA)</td>
</tr>
<tr>
<td>Pharmacy Board of Tasmania</td>
<td>Pharmacists Registration Act 2001 (Tas)</td>
</tr>
<tr>
<td>Pharmaceutical Council of Western Australia</td>
<td>Pharmacy Act 1964 (WA) State Administrative Tribunal Act 2004 (WA) State Administrative Tribunal (Conferral of Jurisdiction) Amendment and Repeal Act 2004 (WA)</td>
</tr>
<tr>
<td>Australian Capital Territory Pharmacy Board</td>
<td>Pharmacy Act 1931 (ACT)</td>
</tr>
<tr>
<td>Pharmacy Board of the Northern Territory</td>
<td>Health Practitioners Act 2004 (NT)</td>
</tr>
</tbody>
</table>

Briefly describe the disciplinary process.

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists Board of Queensland</td>
<td>Board or Committee considers less serious breaches – advice, caution &amp; reprimand and may impose undertakings Professional Conduct Review Panel – may impose conditions Health Practitioners Tribunal for breaches that potentially involve suspension or cancellation of registration.</td>
</tr>
<tr>
<td>Pharmacy Board of New South Wales</td>
<td>Board or Committee considers breaches and may inter alia caution or reprimand, determine practice conditions, impose a fine, suspend registration for up to 12 months or remove person from the register.</td>
</tr>
<tr>
<td>Pharmacy Board of Victoria</td>
<td>Board has 2 process in place: formal hearing for more serious breaches and informal hearing New legislation being developed that will operate from 1 July 2007: Health Professions Registration Act 2005 and powers to suspend or deregister will be the preserve of the Victorian Civil and Administrative Appeals Tribunal (VCAT). Other hearing will remain at board panels, with penalties such as cautions.</td>
</tr>
</tbody>
</table>
pacing conditions on registration, requiring the registrant to undergo specified education or undergo counselling.

**Pharmacy Board of South Australia**
Board considers breaches. S44 - Board may impose conditions, suspend registration for up to 3 years and cancel registration.

**Pharmacy Board of Tasmania**
All complaints are referred to an investigation committee who can determine that a complaint is less serious, in which case it is dealt with by informal disciplinary proceedings or that it is a matter to be referred to a Disciplinary Tribunal. Appeals against Tribunal decisions are to the Supreme Court.

**Pharmaceutical Council of Western Australia**
Complaints are received in writing. The pharmacist is invited to comment. The matter is considered by the Council’s Complaints Assessment Committee which makes a recommendation to the Council. If the Council determines “that a proceeding before the Tribunal is not warranted by the nature of the matter involved”, and after the “accused person” has been offered some choices (Section 32(4) of Pharmacy Act) the Council may deal with the matter. Otherwise, the matter is referred to the State Administrative Tribunal.

The Tribunal has more extensive powers to make orders than does the Council (Section 32).

**Australian Capital Territory Pharmacy Board**
Complaints are assessed and investigated by the Complaints Commissioner.

The Board holds Boards Of Inquiry on matters referred to it by the Commissioner or on its own account.

**Pharmacy Board of the Northern Territory**
S61-65 Board may caution, reprimand, accept undertaking, impose condition, fine (up to $10,000) etc. whereas Professional Review Tribunal may suspend or cancel registration.

Please explain to what extent and at what stage the outcomes of disciplinary cases are available to registrants.

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th>Outcomes Available to Registrants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists Board of Queensland</td>
<td>Board Newsletters may highlight specific practice relevant issues without identifying the pharmacist. Tribunal decisions in newsletters identify pharmacist. Tribunal hearings open to public, decisions part of case law. However, not on Austl II website at the moment and also not on Queensland courts website at present.</td>
</tr>
<tr>
<td>Pharmacy Board of New South Wales</td>
<td>The Board’s decisions are published at <a href="http://www.austlii.edu.au">www.austlii.edu.au</a> immediately they become effective. The Board also publishes a Bulletin approximately once per 12 to 18 months which includes a summary of all disciplinary outcomes.</td>
</tr>
<tr>
<td>Pharmacy Board of Victoria</td>
<td>Formal hearings: in newsletters and on website give full details including registrant name and outcome Informal hearings: in newsletter and log-in area of</td>
</tr>
<tr>
<td>Regulatory Authority</td>
<td>Website give limited details eg. summary of issues and outcome</td>
</tr>
<tr>
<td>----------------------------------------------------------</td>
<td>---------------------------------------------------------------</td>
</tr>
<tr>
<td>Pharmacy Board of South Australia</td>
<td>Examples of cases discussed in newsletters – de-identified. Purpose to make other registrants aware. Obvious breaches/gross misconduct not discussed in newsletter as main purpose is learning tool.</td>
</tr>
<tr>
<td>Pharmacy Board of Tasmania</td>
<td>Details of the substance of all disciplinary matters found proved are publicised in the Board’s Circular, distributed to all registered pharmacists. Individual pharmacists are not normally identified in the circular. The names of pharmacists removed from the register as a result of disciplinary action are published in the Circular, together with summary details of the findings against them.</td>
</tr>
<tr>
<td>Pharmaceutical Council of Western Australia</td>
<td>This is the province of the Tribunal. The Council understands that full disclosure would be made to registrants as soon as is practicable after a matter is concluded.</td>
</tr>
<tr>
<td>Australian Capital Territory Pharmacy Board</td>
<td>The Board publishes its findings.</td>
</tr>
<tr>
<td>Pharmacy Board of the Northern Territory</td>
<td>Board can determine on a case-to-case basis what information to release. S67(4) the Board can publish a notice of the Tribunal decision in any professional publication related to health care.</td>
</tr>
</tbody>
</table>

Please explain to what extent the outcomes of disciplinary cases are available to the general public.

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th>Not available, Tribunal cases open to public</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists Board of Queensland</td>
<td>Austllii is a fully searchable, free database. Copies of specific decisions would be provided by the Board upon request.</td>
</tr>
<tr>
<td>Pharmacy Board of New South Wales</td>
<td>Formal hearing outcomes on website which is available to the general public</td>
</tr>
<tr>
<td>Pharmacy Board of Victoria</td>
<td>Unprofessional conduct cases (more serious outcome cases) notified in press.</td>
</tr>
<tr>
<td>Pharmacy Board of South Australia</td>
<td>Pharmacy Board Circulars are available on the website, summary details are published in the Board annual report, which is tabled in parliament and published together with other health registration board reports.</td>
</tr>
<tr>
<td>Pharmaceutical Council of Western Australia</td>
<td>Section 61 (1) of the State Administrative Tribunal Act 2004 provides &quot;Unless another provision of this Act provides otherwise, hearings of the Tribunal are to be held in public.&quot;</td>
</tr>
<tr>
<td>Australian Capital Territory Pharmacy Board</td>
<td>Hearings are open to the public</td>
</tr>
<tr>
<td>Pharmacy Board of the Northern Territory</td>
<td>Board can determine on a case-to-case basis what information to release. S67(4) the Board can publish a notice of the Tribunal decision in any professional publication related to health care – therefore not the general public.</td>
</tr>
</tbody>
</table>
Has the Board endorsed the Pharmaceutical Society of Australia's Code of Professional Conduct?

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists Board of Queensland</td>
<td>Yes - Board meeting, refer Bulletin 19 Jan 2004</td>
</tr>
<tr>
<td>Pharmacy Board of New South Wales</td>
<td>Yes – although not formally adopted as a guideline it is referred to in Board Bulletins with an expectation that the Code must underpin all activities as a pharmacist.</td>
</tr>
<tr>
<td>Pharmacy Board of Victoria</td>
<td>Yes – adopted in Board Guidelines for Good Pharmacy Practice 2005 version</td>
</tr>
<tr>
<td>Pharmacy Board of South Australia</td>
<td>Yes – formally adopted and repeated in the Board’s “Codes of professional conduct and professional practice”</td>
</tr>
<tr>
<td>Pharmacy Board of Tasmania</td>
<td>Yes - pharmacists in Tasmania must comply with the Pharmacy Code (see Section 10 of the Pharmacists Registration Act 2001). Section 4 of the Pharmacy Code requires pharmacists to comply with all relevant practice standards and specifically mentions the PSA Code of Professional Conduct.</td>
</tr>
<tr>
<td>Pharmaceutical Council of Western Australia</td>
<td>Nor formally</td>
</tr>
<tr>
<td>Australian Capital Territory Pharmacy Board</td>
<td>Yes</td>
</tr>
<tr>
<td>Pharmacy Board of the Northern Territory</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Has the Board endorsed the Pharmaceutical Society of Australia's Professional Practice Standards?

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists Board of Queensland</td>
<td>Yes - Oct 2003 Board meeting, refer bulletin 19 Jan 2004 - Board endorsed all the standards and guidelines in APF 18th edition</td>
</tr>
<tr>
<td>Pharmacy Board of New South Wales</td>
<td>Yes – although not formally adopted as a guideline it is referred to in Board Bulletins.</td>
</tr>
<tr>
<td>Pharmacy Board of Victoria</td>
<td>Yes – adopted in Board Guidelines for Good Pharmacy Practice 2005 version</td>
</tr>
<tr>
<td>Pharmacy Board of South Australia</td>
<td>Yes – the Board’s “Code of professional conduct and professional practice” requires pharmacists to comply with all relevant practice standards and specifically mentions the PSA Professional Practice Standards.</td>
</tr>
<tr>
<td>Pharmacy Board of Tasmania</td>
<td>Yes – Pharmacists in Tasmania must comply with the Pharmacy Code (see Section 10 of the Pharmacists Registration Act 2001). Section 4 of the Pharmacy Code requires pharmacists to comply with all relevant practice standards and specifically mentions the PSA Professional Practice Standards.</td>
</tr>
<tr>
<td>Pharmaceutical Council of Western Australia</td>
<td>Nor formally</td>
</tr>
<tr>
<td>Australian Capital Territory Pharmacy Board</td>
<td>Yes</td>
</tr>
<tr>
<td>Pharmacy Board of the Northern Territory</td>
<td>Yes (check website)</td>
</tr>
</tbody>
</table>
### Has the Board endorsed the Pharmaceutical Society of Australia’s S2/S3 Standards?

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists Board of Queensland</td>
<td>Yes - Initially 22 Oct 2003 and then again highlighted Bulletin 20 Sept 2004</td>
</tr>
<tr>
<td>Pharmacy Board of New South Wales</td>
<td>Yes, with a note that the standards have been endorsed by APRA</td>
</tr>
<tr>
<td>Pharmacy Board of Victoria</td>
<td>Yes – adopted in Board Guidelines for Good Pharmacy Practice 2005 version</td>
</tr>
<tr>
<td>Pharmacy Board of South Australia</td>
<td>Yes, the Board was also involved in an S2, S3 program run through the University of SA.</td>
</tr>
<tr>
<td>Pharmacy Board of Tasmania</td>
<td>Yes – Pharmacists in Tasmania must comply with the Pharmacy Code (see Section 10 of the Pharmacists Registration Act 2001). Section 4 of the Pharmacy Code requires pharmacists to comply with all relevant practice standards and specifically mentions the PSA Professional Practice Standards.</td>
</tr>
<tr>
<td>Pharmaceutical Council of Western Australia</td>
<td>Not formally but it did formally endorse the implementation program of the forerunner – a joint project of the Universities of Sydney and South Australia</td>
</tr>
<tr>
<td>Australian Capital Territory Pharmacy Board</td>
<td>Yes</td>
</tr>
<tr>
<td>Pharmacy Board of the Northern Territory</td>
<td>Yes (check website)</td>
</tr>
</tbody>
</table>

### Has the Board endorsed the Quality Care Pharmacy Program?

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists Board of Queensland</td>
<td>Yes - Board meeting 22 Oct 2003 – refer Bulletin 19 Jan 2004</td>
</tr>
<tr>
<td>Pharmacy Board of New South Wales</td>
<td>No</td>
</tr>
<tr>
<td>Pharmacy Board of Victoria</td>
<td>The Board recognises the Quality Care Program in the Board Guidelines for Good Pharmacy Practice 2005 version</td>
</tr>
<tr>
<td>Pharmacy Board of South Australia</td>
<td>The Board supports the Quality Care Program, however it does not form part of our Codes &amp; Guidelines.</td>
</tr>
<tr>
<td>Pharmacy Board of Tasmania</td>
<td>No. The Pharmacy Code requires that pharmacies have a system of quality assurance but does not specify QCPP</td>
</tr>
<tr>
<td>Pharmaceutical Council of Western Australia</td>
<td>Not formally</td>
</tr>
<tr>
<td>Australian Capital Territory Pharmacy Board</td>
<td>No but the Board supports it</td>
</tr>
<tr>
<td>Pharmacy Board of the Northern Territory</td>
<td>No</td>
</tr>
<tr>
<td>Regulatory Authority</td>
<td>Does the Board have Board specific practice policies, procedures and guidelines?</td>
</tr>
<tr>
<td>--------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Pharmacists Board of Queensland                  | Yes – various documents repeat/overlap with other practice standards  
Policy and Guidelines: Distance dispensing  
Guideline: Dose administration aids  
Guideline: Generic substitution  
Guideline: Guide to good dispensing  
Guideline: Patient counselling                                                                   |
| Pharmacy Board of New South Wales                | The Board publishes guidelines and codes of practice, from time to time in its Bulletins.                                                    |
| Pharmacy Board of Victoria                       | Yes (refer Guidelines), some do overlap with PSA as they were developed before PSA documents, in general they seem to be in addition to the PSA ones and not too much duplication. |
| Pharmacy Board of South Australia                | Yes, although they seem to be in addition to the PSA ones and not repeating.                                                                 |
| Pharmacy Board of Tasmania                        | Yes (refer Code), although they seem to be in addition to the PSA ones and not repeating.                                                     |
| Pharmaceutical Council of Western Australia      | Yes  
• Statement of pharmacists’ professional responsibilities  
• Code of practice fro products containing pseudoephedrine  
• Advertising requirements                                                                            |
| Australian Capital Territory Pharmacy Board      | Yes, although they seem to be in addition to the PSA ones and not repeating.                                                                 |
| Pharmacy Board of the Northern Territory         | Yes – but only deals with registration matters.                                                                                             |

**Briefly explain the Board’s role in the setting of practice standards.**

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th>Briefly explain the Board’s role in the setting of practice standards.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists Board of Queensland</td>
<td>The Board has endorsed all the practice standards and guidelines developed by the professional organisations and relies on the profession to set practice standards. However, has also developed a few overlapping documents as well as others eg. dispensary assistants</td>
</tr>
<tr>
<td>Pharmacy Board of New South Wales</td>
<td>As part of its functions under the Pharmacy Act, the Board from tot time develops and publishes policies and guidelines on a range of matters relating to the practice of pharmacy. The Board sees the development of such guidelines and policies as an integral part of its responsibility to promote and maintain the highest standards of professional conduct and ethics in the pharmacy profession.</td>
</tr>
<tr>
<td>Pharmacy Board of Victoria</td>
<td>The Board has endorsed own Guidelines since 1984 – very pro-active role</td>
</tr>
</tbody>
</table>
| Pharmacy Board of South Australia                | “Codes and Guidelines” document  
The Pharmacy Board of South Australia is responsible for exercising a general oversight over the practice standards of pharmacy. The Pharmacy Board of South Australia |
Board, in cooperation with the community of South Australia and its pharmacists, exercises this function ensuring that the community is adequately provided with pharmaceutical services of the highest standard and with a view to achieving and maintaining professional standards of competence and conduct in the practice of pharmacy.

The Pharmacy Board has developed the document that represents the latest version of the Board’s “Code and Guidelines”. The document is intended to guide pharmacists in decision making concerning practice situations while allowing flexibility in professional judgment. It is important that all pharmacists are familiar with resources such as the Codes and Guidelines that are particular to their area of practice. The Codes and Guidelines include:

- the Pharmacy Board’s interpretation of certain parts of the Pharmacy Act and Regulations; and
- how the Pharmacy Board exercises its discretion in regard to certain parts of the Pharmacy Act and Regulations; and
- what the Pharmacy Board has determined to be the minimum standards of good practice; and
- how the Pharmacy Board expects the duties and responsibilities of pharmacists may be best observed.

<table>
<thead>
<tr>
<th>Pharmacy Board of Tasmania</th>
<th>The Board approves Code (refer previous question)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical Council of Western Australia</td>
<td>Current legislation does not contemplate the Council, as administrator of the Pharmacy Act, setting practice standards.</td>
</tr>
<tr>
<td>Australian Capital Territory Pharmacy Board</td>
<td>The Board has the statutory responsibility</td>
</tr>
<tr>
<td>Pharmacy Board of the Northern Territory</td>
<td>Not clear from legislation. Information supplied and website indicates Board hasn’t really done much in this area.</td>
</tr>
</tbody>
</table>

Please indicate the Board’s policy regarding dispensing bar code scanners eg. whether the Board recommends that pharmacists should use scanners or whether it is a mandatory requirement.

This question is separate to the reference to scanners in the QCPP and specifically refers to Board policy.

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists Board of Queensland</td>
<td>Recommends should have – refer bulletin 17 Nov 2002</td>
</tr>
<tr>
<td>Pharmacy Board of New South Wales</td>
<td>The Board recommends (but does not require) the use of barcode scanners. Refer Newsletter article published September 2005.</td>
</tr>
<tr>
<td>Pharmacy Board of Victoria</td>
<td>Mandatory – one scanner per dispensing workstation</td>
</tr>
<tr>
<td>Pharmacy Board of South Australia</td>
<td>The use of bar code scanners is not mandatory Board policy, though it is recommended.</td>
</tr>
<tr>
<td>Pharmacy Board of Tasmania</td>
<td>The Pharmacy Code requires that all pharmacies have a bar code scanner and that it be used in the</td>
</tr>
</tbody>
</table>
Dispensing procedure.

**Pharmaceutical Council of Western Australia**
The Council was directly and solely responsible for a regulation which mandates scanners in pharmacies – refer Pharmacy Amendment Regulations 2005 now in Appendix C of Pharmacy Act Regulations 1976: 1 per pharmacy.

**Australian Capital Territory Pharmacy Board**
Recommended but the Board avoids prescribing specific technology that may become outdated.

**Pharmacy Board of the Northern Territory**
No specific policy exists.

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Please indicate the Board’s policy regarding individual pharmacists & professional indemnity insurance eg. whether the Board recommends that employee pharmacists should have insurance or whether it is a mandatory requirement. This question is separate to the reference to insurance in the QCPP and specifically refers to Board policy.

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th>Pharmacists Board of Queensland</th>
<th>Recommends should have – refer Bulletin 19 Jan 2004</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pharmacy Board of New South Wales</td>
<td>There is no mandatory requirement for professional indemnity insurance.</td>
</tr>
<tr>
<td></td>
<td>Pharmacy Board of Victoria</td>
<td>All pharmacists are required to have professional indemnity insurance as a condition of registration, minimum of $20 million</td>
</tr>
<tr>
<td></td>
<td>Pharmacy Board of South Australia</td>
<td>Pharmacists in South Australia are unable to practise unless indemnified against loss under Section 30 of the Pharmacists Act 1991.</td>
</tr>
<tr>
<td></td>
<td>Pharmacy Board of Tasmania</td>
<td>All pharmacists are required to have professional indemnity insurance as a condition of registration (section23 (2) of Act)</td>
</tr>
<tr>
<td></td>
<td>Pharmaceutical Council of Western Australia</td>
<td>It is not a mandatory requirement. However, the Council actively and annually promotes and recommends that practitioners hold cover.</td>
</tr>
<tr>
<td></td>
<td>Australian Capital Territory Pharmacy Board</td>
<td>Mandatory in 2007</td>
</tr>
<tr>
<td></td>
<td>Pharmacy Board of the Northern Territory</td>
<td>From policy: practitioners who are employees are entitled to be indemnified by their employer, however there may still be a requirement for the practitioner to hold individual professional indemnity insurer. This needs to be discussed with the employer</td>
</tr>
</tbody>
</table>

---

Please provide information about the Board’s current annual re-registration requirements for pharmacists.

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th>Pharmacists Board of Queensland</th>
<th>Currently pharmacists renew their registration by payment of the annual roll fee.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pharmacy Board of New South Wales</td>
<td>Currently pharmacists renew their registration by payment of the annual roll fee.</td>
</tr>
<tr>
<td></td>
<td>Pharmacy Board of Victoria</td>
<td>As of January 2007 EnrichVic implemented, similar to SA</td>
</tr>
<tr>
<td></td>
<td>Pharmacy Board of South Australia</td>
<td>Pharmacists need to complete the ENRICH program and apply for a Practising Certificate after completing a Personal Declaration of Competency before they</td>
</tr>
</tbody>
</table>
can register. Need to complete 20 Enrich credits/year. Retain competency forms for potential audit.

Pharmacy Board of Tasmania
All pharmacists must sign a declaration that they are competent and that they have maintained a professional portfolio which demonstrates how they have maintained their competence. Portfolios are subject to audit, each year 10% of pharmacists are required to submit their portfolio for assessment.

Pharmaceutical Council of Western Australia
The Council requires applicants for annual renewal of licence to practise who have not practised for three years to present for interview before their application is considered.

Australian Capital Territory Pharmacy Board
Currently pharmacists renew their registration by payment of the annual roll fee.

Pharmacy Board of the Northern Territory
Currently pharmacists renew their registration by payment of the annual roll fee.

Is the Board in the process of developing requirements regarding annual re-registration that would require proof of continuous professional development?

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists Board of Queensland</td>
<td>Draft recency of practice document</td>
</tr>
<tr>
<td>Pharmacy Board of New South Wales</td>
<td>The Board will consider options for ongoing assurance of competence in the near future.</td>
</tr>
<tr>
<td>Pharmacy Board of Victoria</td>
<td>EnrichVic January 2007 implemented</td>
</tr>
<tr>
<td>Pharmacy Board of South Australia</td>
<td>ENRICH system already in place</td>
</tr>
<tr>
<td>Pharmacy Board of Tasmania</td>
<td>System already in place</td>
</tr>
<tr>
<td>Pharmaceutical Council of Western Australia</td>
<td>No. Current government policy opposes this.</td>
</tr>
<tr>
<td>Australian Capital Territory Pharmacy Board</td>
<td>CPD is mandatory in 2007 – how will it be assessed?</td>
</tr>
<tr>
<td>Pharmacy Board of the Northern Territory</td>
<td>No</td>
</tr>
</tbody>
</table>

Is it a requirement of annual re-registration to have a current first-aid certificate?

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists Board of Queensland</td>
<td>No</td>
</tr>
<tr>
<td>Pharmacy Board of New South Wales</td>
<td>No</td>
</tr>
<tr>
<td>Pharmacy Board of Victoria</td>
<td>No</td>
</tr>
<tr>
<td>Pharmacy Board of South Australia</td>
<td>No, only for initial registration</td>
</tr>
<tr>
<td>Pharmacy Board of Tasmania</td>
<td>No - it is a condition of registration but not re-registration, but is an indicator of basic competence, therefore most pharmacists have a current certificate</td>
</tr>
<tr>
<td>Pharmaceutical Council of Western Australia</td>
<td>No</td>
</tr>
<tr>
<td>Australian Capital Territory Pharmacy Board</td>
<td>Yes in 2007</td>
</tr>
<tr>
<td>Pharmacy Board of the Northern Territory</td>
<td>No</td>
</tr>
</tbody>
</table>
Please provide information about the Board’s pre-registration requirements under the following headings:

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th>Required period</th>
<th>Prescribed program(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists Board of Queensland</td>
<td>1824 hours over at least 48 weeks</td>
<td>PSA Qld Branch pre-registration program</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Approved/accredited program providers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PSA Qld Branch</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Assignments</td>
</tr>
<tr>
<td></td>
<td></td>
<td>assignments, OSCE, APCAT from 2007</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Who conducts the final assessment</td>
</tr>
<tr>
<td>Pharmacy Board of New South Wales</td>
<td>2000 hours for graduates from NSW tertiary institutions</td>
<td>Pharmacy Graduate Training Course</td>
</tr>
<tr>
<td></td>
<td>53 weeks for graduates from interstate and New Zealand institutions</td>
<td>Approved/accredited program providers</td>
</tr>
<tr>
<td>Pharmacy Board of Victoria</td>
<td>12 months</td>
<td>PSA (Vic) and Monash University</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Approved/accredited program providers</td>
</tr>
<tr>
<td>Pharmacy Board of South Australia</td>
<td>52 weeks</td>
<td>PEL (Post-graduate Experiential Learning) program</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Approved/accredited program providers</td>
</tr>
<tr>
<td>Pharmacy Board of Tasmania</td>
<td>1 year (52 weeks, less 4 weeks annual leave and 2 weeks course attendance)</td>
<td>Approved/accredited program providers</td>
</tr>
</tbody>
</table>
Graduate Accreditation Program (GAP) is delivered by Clinical Tutors (Board employees)

**Assessments**
- Practice portfolio + APCAT Exam + Oral examination
- Who conducts the final assessment?
  - Board

<table>
<thead>
<tr>
<th>Pharmaceutical Council of Western Australia</th>
<th>Required period: 2500 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Council provides the program: Three two-day seminars, APCAT exam, submission of substantial portfolio of workplace based experience</td>
<td></td>
</tr>
<tr>
<td>Approved/accredited program providers: Pharmaceutical Council of Western Australia. Additionally, through COPRA, all registration authorities have agreed to accept each other’s training for the purpose of registration.</td>
<td></td>
</tr>
</tbody>
</table>

**Assessments**
- see above, plus oral assessment by two panels of examiners at the end of training period
- Who conducts the final assessment?
  - Council

<table>
<thead>
<tr>
<th>Australian Capital Territory Pharmacy Board</th>
<th>No pre-registration program in ACT – meet other State’s requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy Board of the Northern Territory</td>
<td>No pre-registration program in NT – meet other State’s requirements</td>
</tr>
</tbody>
</table>

**Does the Board keep a register of:**
- Pre-registration pharmacists:
- Pharmacy students on placement:

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th>Pre-registration pharmacists:</th>
<th>Pharmacy students on placement:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists Board of Queensland</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Pharmacy Board of New South Wales</td>
<td>Pre-registration pharmacists: Maintain contact list but not formally part of the Register. Will be part of the Register upon commencement of the Pharmacy Practice Act 2006</td>
<td></td>
</tr>
<tr>
<td>Pharmacy students on placement:</td>
<td>- No and no plans</td>
<td></td>
</tr>
<tr>
<td>Pharmacy Board of Victoria</td>
<td>Pre-registration pharmacists: Yes</td>
<td></td>
</tr>
<tr>
<td>Pharmacy students on placement:</td>
<td>&gt; 2nd year)</td>
<td></td>
</tr>
<tr>
<td>Pharmacy Board of South Australia</td>
<td>Pre-registration pharmacists: Yes</td>
<td></td>
</tr>
<tr>
<td>Pharmacy students on placement:</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Pharmacy Board of Tasmania</td>
<td>Pre-registration pharmacists: No</td>
<td></td>
</tr>
<tr>
<td>Pharmacy students on placement:</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical Council of Western Australia</td>
<td>Pre-registration pharmacists: Yes</td>
<td></td>
</tr>
<tr>
<td>Pharmacy students on placement:</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Australian Capital Territory Pharmacy Board</td>
<td>Pre-registration pharmacists: No</td>
<td></td>
</tr>
<tr>
<td>Pharmacy students on placement:</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Pharmacy Board of the Northern Territory</td>
<td>Pre-registration pharmacists: No</td>
<td></td>
</tr>
<tr>
<td>Pharmacy students on placement:</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>
Please provide information about registrants’ English skills requirements.

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th>English Skills Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists Board of Queensland</td>
<td>The Board relies on University and APEC assessments of English</td>
</tr>
<tr>
<td>Pharmacy Board of New South Wales</td>
<td>s. 17(1)(a1) Pharmacy Act 1964 – person proves to the satisfaction of the Board that he has a knowledge of the English language adequate to carry on the business of a pharmacist</td>
</tr>
<tr>
<td>Pharmacy Board of Victoria</td>
<td>S6 of Pharmacy Practice Act 2004 specifies must be competent in speaking and communicating in English</td>
</tr>
<tr>
<td>Pharmacy Board of South Australia</td>
<td>Assessed during the required oral examination.</td>
</tr>
<tr>
<td>Pharmacy Board of Tasmania</td>
<td>The Board relies on University and APEC assessments of English</td>
</tr>
<tr>
<td>Pharmaceutical Council of Western Australia</td>
<td>Pharmacy Act 1964 – Section 22(1)(d) – the person must prove to the Council that “he has such an adequate knowledge of the English language as to be able readily and intelligibly to speak, read and write that language.”</td>
</tr>
<tr>
<td>Australian Capital Territory Pharmacy Board</td>
<td>The Board relies on University and APEC assessments of English</td>
</tr>
<tr>
<td>Pharmacy Board of the Northern Territory</td>
<td>The Board relies on University and APEC assessments of English</td>
</tr>
</tbody>
</table>

Does the Board keep a register of pharmacy support personnel?

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th>Keep Register of Pharmacy Support Personnel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists Board of Queensland</td>
<td>No</td>
</tr>
<tr>
<td>Pharmacy Board of New South Wales</td>
<td>No</td>
</tr>
<tr>
<td>Pharmacy Board of Victoria</td>
<td>No</td>
</tr>
<tr>
<td>Pharmacy Board of South Australia</td>
<td>No</td>
</tr>
<tr>
<td>Pharmacy Board of Tasmania</td>
<td>No</td>
</tr>
<tr>
<td>Pharmaceutical Council of Western Australia</td>
<td>No</td>
</tr>
<tr>
<td>Australian Capital Territory Pharmacy Board</td>
<td>No</td>
</tr>
<tr>
<td>Pharmacy Board of the Northern Territory</td>
<td>No</td>
</tr>
</tbody>
</table>

Does the Board follow a pharmacy inspection schedule?
If yes, please expand on:
- The process and procedure and
- Aspects covered during the inspections.

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th>Pharmacy Inspection Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists Board of Queensland</td>
<td>No</td>
</tr>
<tr>
<td>Pharmacy Board of New South Wales</td>
<td>Yes, the Board employs 2 inspectors who visit every pharmacy in New South Wales at least once per 18 months to ensure continuing compliance with the requirements of the Pharmacy Act 1964 and the Pharmacy (General) Regulations 1998. Section 24C of the Pharmacy Act provides that a</td>
</tr>
<tr>
<td>Pharmacy Board of Victoria</td>
<td>No</td>
</tr>
<tr>
<td>Pharmacy Board of South Australia</td>
<td>No</td>
</tr>
<tr>
<td>Pharmacy Board of Tasmania</td>
<td>No</td>
</tr>
<tr>
<td>Pharmaceutical Council of Western Australia</td>
<td>No</td>
</tr>
<tr>
<td>Australian Capital Territory Pharmacy Board</td>
<td>No</td>
</tr>
<tr>
<td>Pharmacy Board of the Northern Territory</td>
<td>No</td>
</tr>
</tbody>
</table>
person may not carry on the business of a pharmacist in any premises that are not the subject of a current approval of the Board. The inspectors visit new or relocating pharmacy (before approval is granted for the pharmacy to start trading) to ensure compliance with the Act and Regulations.

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy Board of Victoria</td>
<td>Yes – only board in Victoria that has power of entry without a warrant. Aim to visit pharmacies 3 year cycle, however every pharmacy visited in 2006 as was a requirement of new Act that all existing pharmacies had to be approved.</td>
</tr>
<tr>
<td>Pharmacy Board of South Australia</td>
<td>Yes – all pharmacies on a 3 year cycle. Also new pharmacies, not renovations although pharmacists must submit plans for Board approval. Pharmacists get notification of inspection 6 weeks before inspection and then uses self-assessment form to assess the practice. Any differences between self-assessment and inspection discussed.</td>
</tr>
<tr>
<td>Pharmacy Board of Tasmania</td>
<td>No, a one off inspection is held for initial registration of premises.</td>
</tr>
<tr>
<td>Pharmaceutical Council of Western Australia</td>
<td>Currently only new, altered and refurbished pharmacies are inspected for compliance with physical requirements of the regulations. Council is currently advertising for an inspector who will be required to cover the above aspects for all other pharmacies as well as practice standards and procedures</td>
</tr>
<tr>
<td>Australian Capital Territory Pharmacy Board</td>
<td>No – Responsibility of Health Protection Service</td>
</tr>
<tr>
<td>Pharmacy Board of the Northern Territory</td>
<td>No</td>
</tr>
</tbody>
</table>

Please provide information about the requirements for pharmacy premises, equipment and resources. Separate between compulsory requirements and recommended requirements.

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists Board of Queensland</td>
<td>Refer website</td>
</tr>
<tr>
<td>Pharmacy Board of New South Wales</td>
<td>Minimum standards for premises are set out in clause 12 of the Pharmacy (General) Regulation 1998. Clause 17 of that Regulation provides that a person carrying on a pharmacy business must install and maintain in the pharmacy the equipment, appliances and publications listed in Schedule 3 to the Regulation.</td>
</tr>
<tr>
<td>Pharmacy Board of Victoria</td>
<td>Extensive criteria in Guidelines document</td>
</tr>
<tr>
<td>Pharmacy Board of South Australia</td>
<td>References listed in Pharmacy Self-assessment record. Also ventilation, lighting, use of support staff, drug safe etc. requirements. No equipment requirements.</td>
</tr>
<tr>
<td>Pharmacy Board of Tasmania</td>
<td>Requirements detailed in Pharmacy Code</td>
</tr>
<tr>
<td>Pharmaceutical Council of Western Australia</td>
<td>Check regulation 56(1) Also Appendix C with amendments</td>
</tr>
<tr>
<td>Australian Capital Territory Pharmacy Board</td>
<td>Board guidelines will become compulsory standards in 2007 – check print-out</td>
</tr>
<tr>
<td>Pharmacy Board of the Northern Territory</td>
<td>No requirements in NT established by Board</td>
</tr>
</tbody>
</table>
Please provide information on any other premises requirements.

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists Board of Queensland</td>
<td></td>
</tr>
<tr>
<td>Pharmacy Board of New South Wales</td>
<td>NA</td>
</tr>
<tr>
<td>Pharmacy Board of Victoria</td>
<td></td>
</tr>
<tr>
<td>Pharmacy Board of South Australia</td>
<td></td>
</tr>
<tr>
<td>Pharmacy Board of Tasmania</td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical Council of Western Australia</td>
<td>A pharmacy which is not approved to supply benefits under the Pharmaceutical Benefits Scheme is required to prominently display a sign warning patients of the effect of that lack on their rights.</td>
</tr>
<tr>
<td>Australian Capital Territory Pharmacy Board</td>
<td></td>
</tr>
<tr>
<td>Pharmacy Board of the Northern Territory</td>
<td></td>
</tr>
</tbody>
</table>

Does the Board keep a register of pharmacy premises?

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists Board of Queensland</td>
<td>No</td>
</tr>
<tr>
<td>Pharmacy Board of New South Wales</td>
<td>Yes – section 24A of the Pharmacy Act 1964 provides that the Board is to keep a register containing particulars of approved premises and registered owners.</td>
</tr>
<tr>
<td>Pharmacy Board of Victoria</td>
<td>Yes</td>
</tr>
<tr>
<td>Pharmacy Board of South Australia</td>
<td>Yes - location, contact details, ownership</td>
</tr>
<tr>
<td>Pharmacy Board of Tasmania</td>
<td>Yes - Premises Registration restored to the Act, effective 1 September 2006</td>
</tr>
<tr>
<td>Pharmaceutical Council of Western Australia</td>
<td>Yes.</td>
</tr>
<tr>
<td></td>
<td>The Register shows the name, address and methods of contact of the pharmacy and its owners</td>
</tr>
<tr>
<td>Australian Capital Territory Pharmacy Board</td>
<td>No</td>
</tr>
<tr>
<td>Pharmacy Board of the Northern Territory</td>
<td>No</td>
</tr>
</tbody>
</table>
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