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


• HL Hattingh, N Smith, J Searle, M King & K Forrester. “Regulation of the pharmacy profession throughout Australia”, Journal of Pharmacy Practice and Research, in press
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Therapeutic Goods Regulations 1990 (Cwlth)

STATES AND TERRITORIES

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:
Civil Liability Act 2002 (NSW)
Civil Liability Amendment (Personal Responsibility) Act 2002 (NSW)
Pharmacy Act 1964 (NSW)
Pharmacy Practice Act 2006 (NSW)
Poisons and Therapeutic Goods Act 1966 (NSW)
Poisons and Therapeutic Goods Regulation 2002 (NSW)
Northern Territory:
Health Practitioners Act 2004 (NT)
Personal Injuries (Civil Claims) Act 2003 (NT)
Personal Injuries (Liabilities and Damages) Act 2003 (NT)
Poisons and Dangerous Drugs Act 1983 (NT)
Poisons Regulations 1975 (NT)

Queensland:
Civil Liability Act 2003 (Qld)
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)
Health Rights Commission Act 1991 (Qld)
Health Services Act 1991 (Qld)
Personal Injuries Proceedings Act 2002 (Qld)
Pharmacists Registration Act 2001 (Qld)

South Australia:
Controlled Substances Act 1984 (SA)
Controlled Substances (Poisons) Regulation 1996 (SA)
Pharmacists Act 1991 (SA)
Pharmacy Practice Act 2007 (SA)
Recreational Services (Limitation of Liability) Act 2002 (SA)
Volunteers Protection Act 2001 (SA)
Wrongs (Liability and Damages for Personal Injury) Amendment Act 2002 (SA)
Tasmania:
Civil Liability Act 2002 (Tas)
Duties Act 2001 (Tas)
Pharmacists Registration Act 2001 (Tas)
Poisons Act 1971 (Tas)
Poisons Regulations 1975 (Tas)

Victoria:
Drugs, Poisons and Controlled Substances Act 1981 (Vic)
Drugs, Poisons and Controlled Substances Regulations 2006 (Vic)
Health Professions Registration Act 2005 (Vic)
Pharmacy Practice Act 2004 (Vic)
Wrongs and Other Acts (Law of Negligence) Act 2003 (Vic)
Wrongs and Other Acts (Public Liability Insurance Reform) Act 2002 (Vic)
Wrongs and Limitation of Actions Act (Insurance Reform) Act 2003 (Vic)

Western Australia:
Civil Liability Act 2002 (WA)
Insurance Commission of WA Amendment Act 2002 (WA)
Pharmacists Bill 2006 (WA)
Pharmacy Act 1964 (WA)
Poisons Act 1964 (WA)
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)).

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>Description</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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<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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<tr>
<td>NPS</td>
<td>National Prescribing Service</td>
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<tr>
<td>OTC</td>
<td>Over-The-Counter</td>
</tr>
<tr>
<td>PBS</td>
<td>Pharmaceutical Benefits Scheme</td>
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<tr>
<td>Guild</td>
<td>Pharmacy Guild of Australia</td>
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<tr>
<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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<tr>
<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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<tr>
<td>SUSDP</td>
<td>Standard for the Uniform Scheduling of Drugs and Poisons</td>
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S2: Schedule 2

S3: Schedule 3

S2/S3 Standards: Standards for the Provision of Pharmacist Only and Pharmacy Medicines in Community Pharmacy

TGA: Therapeutic Goods Administration

UK: United Kingdom

USA: United States of America

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