Regulation of the Pharmacy Profession throughout Australia

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ABSTRACT

Background: Pharmacy state and territory legislation provides for the regulation of the profession throughout Australia by the pharmacy registering authorities. The Council of Pharmacy Registering Authorities (COPRA) was formed to harmonise these regulatory requirements and facilitate communication among pharmacy registering authorities. COPRA was recently renamed the Australian Pharmacy Council. The Council of Australian Governments (COAG) has made recommendations that will impact on the regulation of all health professionals in Australia.

Aim: To compare the regulatory requirements and identify regulatory consistencies and differences between jurisdictions.

Method: A qualitative approach encompassing a survey and interview was used. All 8 pharmacy registering authorities were approached to participate via an invitation through the Australian Pharmacy Council in September 2006.

Results: Pharmacy registering authorities operate under diverse legislative frameworks and requirements. There are different definitions for disciplinary processes and the extent to which the registering authorities are able to sanction practitioners. The jurisdictions have different requirements for pharmacy premises registration, the inspection of premises and the required equipment and resources to practise. Differences in pre-registration programs, the assessment of pre-registration pharmacists and initial and ongoing registration specifications were also identified.

Conclusion: The Australian Pharmacy Council and the pharmacy registering authorities have made significant progress towards the harmonisation of pharmacy regulation. However, the regulation of the profession throughout Australia remains varied. COAG needs to focus on early reforms such as a national pharmacy register before addressing the complex issues of consistency in disciplinary outcomes, pre-registration programs and annual pharmacist registration requirements.

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INTRODUCTION

The regulation of the pharmacy profession is the principle means of ensuring public trust in the services provided by pharmacists. The regulation of Australian pharmacy dates back to the 19th century with the establishment of colonially-organised pharmaceutical societies.¹ These societies became powerful moulders of Australian pharmacy practice as they produced the first documents detailing organised standards in education, qualifications and ethics. They also influenced the development of pharmacy legislation in each colony or state.¹

Australia has recently started a process of review of the regulatory framework for all health professions. This has been done under the auspice of the Council of Australian Governments (COAG) that, in July 2006, agreed to establish by July 2008 a single national registration scheme for all health professionals. The purpose of the single scheme would be to

facilitate workforce mobility, improve safety and quality, and reduce bureaucracy.² These recommendations have high level support from the Prime Minister and state and territory leaders. The COAG recommendations have the potential to cause major reforms in the regulation of all health professionals in Australia.

History of Pharmacy Regulation

In the 1870s, Victoria and New South Wales (NSW) were the first jurisdictions to introduce pharmacy boards as entities separate from the society councils.^{1,3} The creation of the pharmacy boards, as independent bodies separate from the professional organisations, established the principle that the boards existed for the protection of the public and acted in the interest of consumers whereas the societies acted on behalf of their members. This approach was followed by all the other jurisdictions, except Western Australia (WA). The process of separating roles in WA has also commenced through the drafting of the *Pharmacists Bill 2006*.

The separation of roles in Australia was a departure from the English precedent. However, the UK structure has often been criticised and following an extensive review the regulatory role of the Royal Pharmaceutical Society of Great Britain will be taken over by a General Pharmaceutical Council in the near future.⁴⁻⁸ In New Zealand the regulatory and professional representative roles were separated in 2004.^{9,10}

Role of the Pharmacy Registering Authorities

State and territory legislation provides for the regulation of the profession throughout Australia by pharmacy registering authorities. The authorities have responsibility for the registration and discipline of registered pharmacists. In contrast, the professional pharmacy organisations represent their members. What is in the interest of the public is often also in the interest of the profession and the roles of the registering authorities and the professional organisations thereby overlap to some extent. There is a degree of co-regulation between the authorities and the professional organisations. This overlap in functions is evident in practice standards; the professional organisations determine the standard of practice through the development of practice standards, and the standards are then used by the authorities as a frame of reference when conducting professional hearings.¹¹

Pharmacy registering authorities maintain a register of pharmacists, approve pharmacy premises, oversight 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. Although there are some similarities between the legislative provisions and the powers and the structures of the individual authorities, there are various inconsistencies. In an attempt to *inter alia* harmonise procedures and facilitate communications between pharmacy registering authorities, the Association of Pharmacy Registering Authorities was formed in the early 1990s and was succeeded by the Council of Pharmacy Registering Authorities (COPRA) in 2002, which was renamed the Australian Pharmacy Council (APC) in July 2007.¹² The APC, through the New Zealand and Australian Pharmacy Schools Accreditation Committee, also accredits pharmacy schools to ensure national consistency of university pharmacy courses.¹²

Although the APC and the pharmacy registering authorities have made some progress towards harmonisation, many of the

legislative requirements still vary significantly among states and territories. These differences influence the way pharmacy is practised in the various jurisdictions and the risk management procedures that need to be implemented and followed by pharmacists.

The aim of this study was to compare the regulatory requirements and identify regulatory consistencies and differences between jurisdictions. The findings will be relevant to the current COAG reforms as they provide an overview of the pharmacy regulatory requirements that are currently in place.

METHOD

A qualitative approach encompassing a survey and interview was used. The cohort, comprising all eight pharmacy registering authorities, was approached to participate via an invitation through the APC in September 2006. Data from closed and open-ended questions were analysed using standard thematic coding and categorisation, and theory development. Further data were obtained through searching the pharmacy registering authorities’ web sites. Follow-up interviews were conducted with representatives of the pharmacy registering authorities to clarify certain issues. The regulatory requirements and processes imposed through the various authorities were compared to identify consistencies and differences. Ethical approval for this study was obtained from the Griffith University Human Research Ethics Committee. The return of the questionnaires by the pharmacy registering authorities was taken as implicit consent to participate. All eight pharmacy registering authorities agreed to participate.

RESULTS

Legislative Framework

Table 1 lists the primary legislation that provides for the establishment of the pharmacy registering authorities, the registration of pharmacists and the management of complaints, investigations and disciplinary processes. The Australian Capital Territory (ACT) and the Northern Territory (NT) each have one Act that provides for the registration and discipline of all health professionals. In Victoria the *Health Professions Registration Act 2005*, which came into force on 1 July 2007, similarly resulted in all health professions coming under a single Act. In Queensland (Qld) the provisions dealing with practice standards and discipline have been split away from legislation addressing registration requirements. Queensland’s *Health Practitioner (Professional Standards) Act 1999* deals with the discipline of all health professionals, except nurses. The movement for states and territories to have one legislation for disciplinary processes and outcomes for all health professionals is aimed at improving consistency across disciplines.

In addition to the disciplinary processes followed by the registering authorities, there are health complaints commissions in every state and territory, handling service complaints.¹³ Complaints are managed between the relevant commission and registration board, depending on the nature of the complaint.

Membership

In all seven jurisdictions with pharmacy boards, the majority of members must be pharmacists that are either nominated, elected and/or appointed by the registrants and/or professional organisations and universities; or appointed by Governors/Ministers. Membership of all of the boards includes community representation. The Pharmaceutical Council of WA consists of elected pharmacists only.

Conduct Warranting Disciplinary Action

The provisions in the legislation that identify conduct or behaviour by a pharmacist generating disciplinary proceedings are not uniform across the jurisdictions. For example, in NSW and Qld the term ‘professional misconduct’ is used. However, the definitions of the term, as provided under the respective legislation in each of the states differ significantly. While Victoria and South Australia (SA) both use the term ‘unprofessional conduct’ the definition in each of the jurisdictions is different. There is a degree of inconsistency with regard to the terms used as well as the meanings assigned to similar terms.

All jurisdictions have similar step-wise processes with regard to disciplinary processes. There is, however, a significant difference between the powers of the various authorities to impose sanctions. For example, in Qld, WA, and the ACT the cancellation or suspension of registration is reserved for Tribunals. The new Victorian and NSW legislation will similarly strip those Boards of the power to suspend or deregister practitioners. In comparison, the Pharmacy Boards of SA, Tasmania and the NT have the power to both suspend registrations for up to three years and cancel registrations.

Practice Standards and Guidelines

All of the jurisdictions have adopted the Pharmaceutical Society Code of Professional Conduct. Therefore, there is an overall expectation that the Code underpins all activities performed by pharmacists throughout Australia. The professional standards developed by the professional organisations have been incorporated into policies. However, varied terminology has been used by the different jurisdictions to describe the integration. For example, the Pharmaceutical Society of Australia (PSA) Professional Practice Standards, the Standards for the Provision of Pharmacist Only and Pharmacy Medicines in community pharmacy (S2/S3 Standards) and the Society of

Table 1. Australian pharmacy regulation legislation

Authority	Legislation for establishment of authority	Legislation for disciplinary process
Pharmacy Board of the Australian Capital Territory	<i>Health Professionals Act 2004</i>	<i>Health Professionals Act 2004</i>
Pharmacy Board of New South Wales	<i>Pharmacy Act 1964, Pharmacy Practice Act 2006</i> (to commence on a date to be specified)	<i>Pharmacy Act 1964</i>
Pharmacy Board of the Northern Territory	<i>Health Practitioners Act 2004</i>	<i>Health Practitioners Act 2004</i>
Pharmacists Board of Queensland	<i>Pharmacists Registration Act 2001</i>	<i>Health Practitioner (Professional Standards) Act 1999</i>
Pharmacy Board of South Australia	<i>Pharmacists Act 1991, Pharmacy Practice Act 2007</i> (to commence in 2007 or 2008)	<i>Pharmacists Act 1991</i>
Pharmacy Board of Tasmania	<i>Pharmacists Registration Act 2001</i>	<i>Pharmacists Registration Act 2001</i>
Pharmacy Board of Victoria	<i>Health Professions Registration Act 2005</i> (commenced on 1 July 2007)	<i>Health Professions Registration Act 2005</i>
Pharmaceutical Council of Western Australia	<i>Pharmacy Act 1964, Pharmacists Bill 2006</i> (submission to Parliament in August 2008)	<i>Pharmacy Act 1964</i>

Hospital Pharmacists of Australia Practice Standards were either endorsed, adopted, or referred to in board publications without being formally adopted.

Therefore, a difference exists in the extent to which the 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.¹⁴ Similarly, the Quality Care Pharmacy Program has been ‘endorsed’ by Qld, ‘recognised’ by Victoria and ‘supported’ by SA and the ACT.

Individual practitioner professional indemnity insurance is mandatory in Victoria, SA, Tasmania, the ACT and NSW, with the remaining jurisdictions recommending individual insurance.

Pharmacy Ownership, Premises and Equipment

Community pharmacy ownership provisions in the jurisdictions are complicated and under continuous review. Ownership is in general restricted to pharmacists. Provisions exist in all of the jurisdictions to enable friendly societies to own pharmacies, except the ACT. The NT legislation provides for Aboriginal health services to own pharmacies. The number of pharmacies a pharmacist can own or co-own also varies with no restrictions in the two territories, WA allowing two, Tasmania and SA four while the other states allow five.

Premises registration occurs in NSW, Victoria, SA, Tasmania and WA. The other three jurisdictions do not require premises registration and are therefore limited in the level of control over pharmacy premises and the ability to address deficiencies. Pharmacy inspection schedules are only followed in NSW, Victoria, SA and WA. Whereas NSW conducts inspections on an 18-month cycle and WA on an 18-month to two-year cycle, Victoria and SA follow a three-year cycle.

The requirements with regard to the equipment, appliances and resources that need to be kept in pharmacies also vary considerably between the jurisdictions. The use of dispensing bar code scanners is mandatory in Victoria, Tasmania and WA whereas in the other jurisdictions their use is only recommended.

Pharmacist Annual Registration

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, such as:¹⁵⁻¹⁷

- the SA Enrich program which requires registrants to complete a personal declaration of competency in their area of practice and to complete a specified number of continuous education credits per year;
- EnrichVic (similar to SA Enrich) was implemented by Victoria in January 2007;
- in Tasmania 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;¹⁸ and
- NSW will consider options for ongoing assurance of competence in the near future.

Government policy in WA opposes the implementation of annual re-registration requirements that need proof of continuous professional development. The Pharmacy Boards of Victoria, SA, NT and ACT issue pharmacists with annual practising certificates. The Pharmaceutical Council of WA similarly issues pharmacists with a licence to practice whereas the Pharmacy Boards of NSW and Tasmania issue registration cards. An online public register has to be accessed to ensure a pharmacist has current registration in Queensland.

Pre-Registration Pharmacist Training and Registration

The pre-registration requirements and programs differ considerably between jurisdictions. The ACT and NT do not offer training programs and require pre-registration pharmacists to enrol in interstate programs. The ACT is in the process of introducing its own program. 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. Victoria, SA and Tasmania similarly require 12 months or 52 weeks with 4 weeks leave included;
- NSW requires 2000 hours for students who have completed their tertiary education in NSW and 52 weeks of supervised training for interstate graduates; and
- WA requires 2500 hours of supervised training (significantly more than the other states). However, 500 hours may be completed in a pharmacy in WA prior to attainment of a pharmacy degree.

In Qld, NSW and Victoria the state branches of the PSA are the training program providers. Monash University is also a training provider and therefore Victoria is the only state with two training providers. In SA, Tasmania and WA, the registering authorities themselves provide the training programs.

All of the states conduct a number of assessments consisting of both written and oral components. All of the jurisdictions use the PSA’s Competency Standards as a frame of reference to assess pre-registrants’ competence.¹⁹ As of 2007, all states require pre-registrants to pass the Australian Pharmacy Competency Assessment Test, providing an opportunity to benchmark pre-registrants Australia-wide. Of interest is the situation in Qld where the Pharmacists Board does not conduct a final assessment of the pre-registrants. The entire assessment process has been delegated to the PSA (Qld) and the Board has no direct control over the assessment and achievement of standards for pre-registration pharmacists.

The Australian Pharmacy Examining Committee, a standing committee of the Australian Pharmacy Council, oversees the registration of overseas-trained pharmacists.¹² All overseas-trained pharmacists are required to be assessed for competency to practise in Australia through a formal 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 also registers pre-registration pharmacists and NSW, with the commencement of the *Pharmacy Practice Act 2006*, will register pre-registration pharmacists in the future. The other states maintain records of pre-registration details, which include the location, the name of the supervisor and commencement and completion dates. Victoria is the only state that registers pharmacy students (> 2nd year). None of the jurisdictions maintain registers of pharmacy support staff.

DISCUSSION

The results highlight the diversity of legislation under which the pharmacy registering authorities operate and the variation in the roles of the authorities in the various jurisdictions. Different definitions apply with 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 use of the practice standards developed by the professional organisations. These differences directly impact on administration processes and the extent to which the standards are used in disciplinary processes, decisions and outcomes.

Significant differences were also identified with regard to pharmacy premises registration, the inspection of premises and the equipment that must be kept on premises. Such differences directly impact on practice risk management procedures. For example, as dispensing bar code scanners are only mandatory in three jurisdictions, there may be differences in dispensing processes and risk management procedures implemented by pharmacists between jurisdictions. Differences between pre-registration programmes and the assessment of pre-registration pharmacists were also identified. Although the training programs and the assessments vary, all of the jurisdictions use the PSA Competency Standards to assess the level of competence. Initial and ongoing registration specifications of pharmacists also differed throughout Australia, resulting in different requirements regarding proof of competence throughout the jurisdictions.

Comparing the state and territory pharmacy regulatory requirements shows 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 through the inconsistencies that apply to initial and ongoing registration and proof of continuous professional development. These inconsistencies are further complicated by the variation in the processes and procedures that pharmacists are required to follow in the provision of pharmaceutical services. Importantly, such inconsistencies in the regulation of the profession can impact on the quality of pharmaceutical services provided throughout Australia.

The pharmacy registering authorities have, through the APC, already made some positive moves towards harmonisation and uniformity of qualifications and professional standards, despite the disparity in the legislative provisions. This study's findings highlight those current differences that impact on the regulation of pharmacists and pharmacy practice between the jurisdictions and can further inform these reforms.

CONCLUSION

The APC has made submissions to COAG highlighting that the APC was established with support from the pharmacy registering authorities in the recognition that national registration was both desirable and inevitable.²⁰ Although the ongoing role of the APC following the proposed reforms is unclear, it may be an opportunity for its current powers to be broadened and thereby facilitate pharmacy regulatory consistency.

Clearly transferability of qualifications and scope of practice across jurisdictions is challenging, even in a country of a relatively small population. Reform of the Australian framework for pharmacy regulation under the direction of the recent COAG initiative will therefore be difficult. The proposed move to create an overarching national regulation and accreditation mechanism is likely to be thwarted at many levels due to the complexity of and the large discrepancies in the current system. COAG may need to be focused on some 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.

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