Interstate dispensing: A case for uniform, intuitive legislation

Nijole L Bernaitis, Michelle A King and Denise L Hope

Australian health practitioner registration is national, whereas legislation regarding the handling of medicines is governed by individual States and Territories. To align with the July 2010 national registration scheme some legislative modifications were made concerning scheduled drugs and poisons, but many differences between jurisdictions remain. In Queensland, the Health (Drugs and Poisons) Regulation 1996 (Qld) allows for dispensing of controlled drugs written by interstate prescribers but not lower scheduled specified restricted and regulated restricted drugs. The aim of this study was to assess awareness of seemingly counterintuitive legislation by pharmacists practising in South-East Queensland. Of 125 Gold Coast pharmacies contacted, 54 (43.2%) agreed to participate. The majority of pharmacists (88.9%) had good knowledge regarding controlled drugs. In contrast, they demonstrated confusion regarding specified restricted and regulated restricted drugs (51.9% correct awareness). Uniform legislation between jurisdictions or more intuitive legislation would ease practitioner confusion.

INTRODUCTION

Despite national registration of Australian health practitioners and prior recommendations to strive for national uniformity in medicines legislation, the regulatory aspects of medicines supply are still governed by individual States and Territories. The Australian Health Practitioners Regulation Agency implemented national registration and accreditation of health practitioners from 1 July 2010, effectively removing barriers for health professionals to practise in any jurisdiction. Each jurisdiction’s legislative instrument(s) outline requirements for the supply, prescribing and handling of medicines within that State or Territory, as per the classifications under the Poisons Standard. The Poisons Standard groups medicines according to their level of risk to individuals and the community, corresponding with increasing levels of regulatory control. Schedule 2 pharmacy medicines are available from a pharmacy, Sch 3 pharmacist-only medicines require direct pharmacist supervision for supply, Sch 4 are prescription-only medicines and Sch 8 controlled drugs “require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or moral harm to the extent possible.”

The Poisons Standard 2013 not only outlines the classifications for their risk but also requirements for their supply. Each of the 5 schedules has distinct and separate regulatory requirements, which is to ensure that medicines are appropriately available for use. Schedule 2 pharmacy medicines are available from a pharmacy, Sch 3 pharmacist-only medicines require direct pharmacist supervision for supply, Sch 4 are prescription-only medicines and Sch 8 controlled drugs “require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or moral harm to the extent possible.”


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See Health Practitioner Regulation National Law Act 2009 (Qld).


Therapeutic Goods Administration, National Coordinating Committee on Therapeutic Goods (NCCTG), http://www.tga.gov.au/archive/committees-nctg.htm. This committee was abolished in 2013.
psychological dependence”. Even though some amendments were made to individual State and Territory drugs and poisons legislation to accommodate national registration, there remain many differences between jurisdictions.

In Queensland, the Health (Drugs and Poisons) Regulation 1996 (Qld) and its amendments are subordinate to the Health Act 1937 (Qld) and detail the legislative requirements relating to medicines and poisons. Prior to July 2010, Queensland pharmacists could not dispense prescriptions for certain medicines written by a prescriber not registered in Queensland, including Sch 8 controlled drugs, such as morphine and oxycodone. Since national registration in July 2010, Queensland pharmacists can legally dispense Sch 8 medicines written by interstate prescribers, including regulated controlled drugs, such as dexamphetamine and methylphenidate. Regulated controlled drugs are a subcategory of Sch 8 in Queensland and have additional conditions stated in the Regulation. Despite these changes to Sch 8 medicines, other requirements of Queensland legislation remain intact for certain Sch 3 and Sch 4 medicines, prohibiting the dispensing of interstate prescriptions. Pharmacists cannot dispense specified restricted drugs unless the address of the authorised prescriber on the prescription is in Queensland. Specified restricted drugs include anabolic steroids, ephedrine, pseudoephedrine and the subcategory of regulated restricted drugs, for example, isotretinoin and clomiphene.

Challenges for health practitioners are associated with State variation in the categorisation and nomenclature of medicines, and variation in each jurisdiction’s legislation relating to these categories. Pharmacists practising in border regions are most likely to encounter interstate prescriptions and variation in State legislation. Changes to Queensland law following national registration may cause confusion due to Sch 8 medicines having fewer restrictions on their supply, such as no restriction on prescriber address, than some lower scheduled medicines. This situation seems to be counterintuitive. The aim of this study was to assess the knowledge of South-East Queensland pharmacists, due to their proximity to the New South Wales State border, in relation to the legalities of dispensing interstate prescriptions.

**METHOD**

Pharmacies across the Gold Coast area of South-East Queensland were identified via an internet search. Telephone calls were made in October 2013 to each of these pharmacies and the pharmacist was informed about the study and asked to participate. If consent was obtained, participants were asked a number of questions based on their demographics and the research objectives. Demographic questions related to whether the pharmacist supervised pharmacy students, was a member of a professional pharmacy organisation, and the year in which the pharmacist first registered as a pharmacist. Research questions asked whether the pharmacist would dispense an interstate prescription for certain categories of medicines defined under the Health (Drugs and Poisons) Regulation 1996 (Qld), with two examples of medicines provided for each category. The categories

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6 Therapeutic Goods Administration, n 4, p iv.
8 Therapeutic Goods Administration, n 4.
9 Queensland Health, n 7.
10 Health (Drugs and Poisons) Regulation 1996 (Qld), Ch 2, Pt 3.
11 Queensland Health, n 7.
12 According to the Health (Drugs and Poisons) Regulation 1996 (Qld), s 193A, Authorised prescriber: “(1) A dispenser must not dispense a restricted drug on a prescription unless – (a) the dispenser reasonably believes the prescription was made by a person (an authorised prescriber) who, under this regulation, is endorsed to prescribe the drug; and (b) if the drug is a specified restricted drug – the address of the authorised prescriber on the prescription is in Queensland. (2) In this section – specified restricted drug means the following restricted drugs – (a) a regulated restricted drug; (b) anabolic steroidal agents; (c) ephedrine; (d) pseudoephedrine.”
were controlled drugs, regulated controlled drugs, specified restricted drugs and regulated restricted drugs. University ethics approval was granted (PHM/03/13/HREC).

Responses were manually recorded and then entered into the Statistical Package for the Social Sciences (SPSS 22 Inc) for descriptive and inferential statistical analysis. Responses to questions about the dispensing of interstate prescriptions were recorded as “yes”, “no” or “unsure”. “Unsure” indicated pharmacists would need to check legislation before proceeding. Year of registration was re-coded to pre-2010 or later to correlate with national registration.

RESULTS

Telephone calls were made to the 125 pharmacies identified in the Gold Coast area, of which 54 (43.2%) agreed to participate. The majority of pharmacists (88.9%) correctly stated that they could dispense an interstate controlled drug prescription (Table 1). A reduced number (72.2%) stated they could dispense an interstate regulated controlled drug prescription (the correct response). There was little uncertainty in the responses concerning controlled drugs prescriptions, with only one respondent (1.9%) unsure of the course of action.

The legalities associated with specified restricted drugs and regulated restricted drugs caused greatest confusion. Interstate prescriptions for these medicines would not have been dispensed by 51.9% of respondents (the correct response for each category). Uncertainty on the part of pharmacists was more evident than with controlled drugs, with 14.8% and 7.4% respectively unsure of how to proceed with interstate prescriptions for specified restricted and regulated restricted drugs. Statistical analysis of the data failed to identify any significant correlation between responses and demographic details.

<table>
<thead>
<tr>
<th>TABLE 1 Pharmacists’ responses to dispensing of interstate prescriptions</th>
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<tbody>
<tr>
<td>Category</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>------</td>
</tr>
<tr>
<td>Controlled drugs (eg morphine, oxycodone)</td>
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<tr>
<td>Regulated controlled drugs (eg dexamphetamine, methylphenidate)</td>
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<tr>
<td>Specified restricted drugs (eg pseudoephedrine, anabolic steroids)</td>
</tr>
<tr>
<td>Regulated restricted drugs (eg isotretinoin, clomiphene)</td>
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DISCUSSION

Controlled drugs
The South-East Queensland pharmacists surveyed appeared to have good knowledge of current legislation concerning the dispensing of Sch 8 controlled drugs, such as morphine or oxycodone. The majority correctly identified that they would dispense an interstate prescription for a controlled drug; however, over a quarter of pharmacists would have refused to dispense a legal interstate prescription for a regulated controlled drug, such as dexamphetamine or methylphenidate. Regulated controlled drugs require additional notation on the prescription to indicate approval granted by the Chief Executive. Pharmacists may be aware of additional legislation relating to this subcategory of Sch 8 medicines but would be uncertain as to the details, which may account for the larger proportion of incorrect responses (27.8%) compared to the other controlled drugs (9.3%). Lack of awareness of

13 Health (Drugs and Poisons) Regulation 1996 (Qld), Ch 2, Pts 3, 4 and Ch 3, Pts 3, 4.
14 Health (Drugs and Poisons) Regulation 1996 (Qld), s 79(j), (k).
medicines legislation could translate to refusal to dispense otherwise legal prescriptions for regulated controlled drugs in Queensland, potentially disrupting the continuity of patient care and bringing the profession into disrepute.

**Restricted drugs**

In contrast to controlled drugs, South-East Queensland pharmacists demonstrated confusion in relation to specified restricted drugs, including the regulated restricted drugs. While the prohibition concerning the dispensing of interstate controlled drug prescriptions was removed at the time of national registration, a Queensland prescriber’s address is still required for regulated restricted drugs and specified restricted drugs. Just over half the respondents (51.9%) correctly identified the legal restriction against dispensing interstate prescriptions for these medicines in Queensland. Of concern is that more than a third of all pharmacists surveyed would dispense an illegal interstate prescription for a specified restricted drug (33.3%) or a regulated restricted drug (40.7%). Pharmacists unaware of the nuances of the State legislation could inadvertently breach the law by supplying otherwise valid prescriptions for some restricted drugs, placing them in legal and professional peril. It is counterintuitive for certain restricted drugs to have more conditions on their supply than controlled drugs and this may contribute to the misunderstandings surrounding the dispensing of interstate prescriptions for these medicines.

**Other research**

An Australian review conducted in 2000, the **National Competition Review of Drugs, Poisons and Controlled Substances Legislation** (known as the Galbally Review), recommended the adoption of national uniformity in drugs and poisons legislation. This was then accepted and supported by the Australian Health Ministers’ Advisory Council. However, these recommendations have not been enacted to date. Other literature supports the view that the supply of medicines in Australia is complicated by the division of regulatory aspects between the Commonwealth Government and the States and Territories. The Commonwealth oversees the registration of health practitioners, the subsidy of medicines under the national Pharmaceutical Benefits Scheme and the scheduling of medicines, whereas the regulation of drugs and poisons handling is the responsibility of the States, and can vary between jurisdictions. Research has identified the potential for State and Territory variation in legislation to cause health practitioner confusion, particularly as health practitioners are likely to be versed in the legislation of their home State or Territory.

**Potential implications**

While national registration of health practitioners has removed barriers to practising interstate, the varying State and Territory-based drugs and poisons legislation has the potential to confuse practitioners, particularly where regulatory requirements appear counterintuitive. Compounding this is the proximity to State borders of many health professionals’ practice. Working near, and across, State

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15 Queensland Health, n 7.
16 Health (Drugs and Poisons) Regulation 1996 (Qld), s 193A
17 Galbally, n 2.
21 Therapeutic Goods Administration, n 4.
22 Tan et al, n 20.
23 Tan et al, n 19.
24 Tan et al, n 19.
borders may cause confusion as to the exact requirements in each State for medicines supply. As demonstrated in this study, failure to be conversant with legal requirements for interstate prescriptions has two potential adverse outcomes: a negative impact on patients’ continuity of care if legal prescriptions are not dispensed, and exposing pharmacists to legal and professional peril if illegal prescriptions are dispensed.

**Recommendations**

Consistent with prior recommendations and particularly following the national registration of Australian health practitioners, it would be desirable to implement uniform national drugs and poisons legislation, to alleviate jurisdiction variation and the potential for confusion. With regard to specific individual State and Territory legislation, such as the Queensland example studied, a progression toward more intuitive legislation is recommended. For example, restricted Sch 3 or Sch 4 medicines should not have higher regulatory requirements, such as requiring a Queensland prescriber address, than Sch 8 controlled drugs, of arguably higher risk. In the absence of legislative change, further education of pharmacists is required to ensure complete understanding of the legal requirements for interstate prescriptions.

**Limitations**

The small sample size may not be indicative of the entire State. Similarly, the sample size may have been too small to identify any demographic variations. This study investigated Queensland legislation and the potential impact of working near the New South Wales border. Further research would be required to assess variations at other State borders and determine if the State where education is acquired impacts on knowledge of State differences in nomenclature and legislation.

**Conclusion**

Despite the national registration of practitioners, numerous differences still remain in legislation regarding the provision of scheduled drugs and poisons in different jurisdictions. The onus is on pharmacists to be conversant with the legislation regarding the dispensing of prescriptions pertinent to their jurisdiction of practice, particularly if practising in areas near State borders. In Queensland, the current legislation is counterintuitive and complicated by the numerous categories of medicines. While further education would be beneficial, the confusion could be removed by uniform, intuitive legislation.

25 Galbally, n 2; Australian Health Ministers’ Advisory Council Working Party, n 2.