State-based legal requirements for Schedule 8 prescriptions: why so complicated?

Inconsistent prescription requirements between Australian states and territories create unnecessary complexity for health professionals

n Australia, medicines defined as Schedule 8 (S8) under the Standard for the Uniform Scheduling of Medicines and Poisons are strictly regulated because of the high risk of misuse and/or physical and psychological dependence associated with them. They have to be prescribed, dispensed, documented and destroyed in specific ways that are in compliance with each state and territory's different drug regulations. S8 medicines are under stricter control than Schedule 4 (S4) medicines (other prescription-only drugs), for which requirements have been standardised between states and territories. 2,3

Australia has no central body to regulate the handling of S8 drugs. Although the Therapeutic Goods Administration (TGA) is the national body for the regulation of medicines, each state and territory self-regulates under the general principles established by the TGA and has its own interpretation and legislation regarding S8 drugs, resulting in varied prescribing requirements. The legal requirements for obtaining authority and writing prescriptions for S8 medicines are listed in Box 1 and Box 2: they are often difficult to find and are long and daunting to read.

Impact on practice

The establishment of a national registration agency, the Australian Health Practitioner Regulation Agency (AHPRA), in 2010 meant that Australian health professionals were allowed to freely practise in any state or territory. Greater mobility of health practitioners between jurisdictions has been accompanied by new problems.

First, to the best of our knowledge, prescribers newly relocated to a different state or who practise across more than one jurisdiction have no single, clear resource that documents the slight nuances in each state or territory's regulations. Legal requirements for prescribing S8 drugs are not accessible in a prescriber-friendly manner. Pharmacists can guide prescribers on the regulations and legality of prescriptions; yet the same confusion applies to pharmacists who move interstate.

Second, travelling patients bringing an S8 prescription interstate might discover that a legal prescription in one



"the table we provide here minimises the ambiguity in legal requirements"

Andy C Hua

Finna Shen

Xiaoting Ge RN, CCRN

Australian National University Medical School, Canberra, ACT.

u5512241@anu.edu.au

doi: 10.5694/mja14.01587

state is not legal in another. The dispensing pharmacist would need to contact the medical practitioner in the patient's home state to find a solution. If this could not be done, treatment would be delayed until a local prescription was obtained from a medical practitioner in the state the patient was visiting.

What can we do?

It may be impractical to unify health care legislation in Australia to eliminate the complexity. However, all states and territories could maintain individual regulations but unify the S8 legal requirements. Given that S4 requirements are standardised between the different states and territories, why are S8 requirements treated differently?

For the moment, resources highlighting state-based S8 requirements for prescribers should be made readily available. A comprehensive quick-reference guide, such as the table we provide here, minimises the ambiguity in legal requirements for health practitioners, and its use may also reduce the amount of time spent by pharmacists and doctors in correcting non-compliant prescriptions.

Competing interests: No relevant disclosures.

Provenance: Not commissioned; externally peer reviewed.

© 2015 AMPCo Pty Ltd. Produced with Elsevier B.V. All rights reserved.

References are available online at www.mja.com.au.

State or territory	Some conditions that require authority	Further informaton	
Australian Capital Territory ⁴	Authority from Chief Health Officer (CHO) when prescribing an S8 drug for > 2 months; when prescribing for a patient who has been prescribed an S8 drug in the previous 2 months; or when prescribing for drug-dependent patients.	ACT Health Pharmaceutical Services: tel (02) 6205 0998	
	The words "CHO approval number" followed by the identifying number for the approval must be annotated on prescriptions for S8 drugs. Approval numbers are issued by the CHO.		
	A prescriber may prescribe an S8 drug for the initial short-term treatment of a non-drug dependent person (for treatment < 2 months) under a standing controlled medicines approval.		
	The words "Standing short term approval" must be written on S8 prescriptions issued under this authority.		
New South Wales ^{5,6}	Authority from Director-General when prescribing a type B drug of addiction for continuous therapeutic use by a person for a period exceeding 2 months; when prescribing a type A drug of addiction; or when prescribing a type C drug of addiction to a drug-dependent person. Type C drug of addiction refers to any drug of addiction other than a type A drug of addiction. (For complete list of type A and type B drugs of addiction, refer to Poisons and Therapeutic Goods Regulation 2008, cll 122, 123.)	NSW Health Pharmaceutical Services: tel (02) 9391 9944	
Northern Territory ⁷⁻⁹	Authority from CHO when prescribing an unrestricted S8 substance for > 15 patients on an ongoing basis; before prescribing a restricted S8 psychostimulant (dexamphetamine, lisdexamfetamine or methylphenidate); or before prescribing a restricted S8 substance for opioid substitution treatment (buprenorphine, buprenorphine/naloxone, methadone liquid).	NT Department of Health Medicines & Poisons Control: tel (08) 8922 7341	
	Notification to CHO when treatment > 8 cumulative weeks in the previous 12 months; if certain dosage levels of increments are exceeded; or if possible misuse of the prescription is suspected.		
Queensland ¹⁰	Authority approval from Chief Executive when treating a drug-dependent person with an S8 drug; when prescribing any specified condition drug other than for attention deficit disorder or brain damage in a child or for treatment of narcolepsy; or before prescribing dronabinol.	Queensland Health Medicines Regulation and Quality: tel (07) 3328 9890	
	Notification to Chief Executive when treating a person with an S8 drug for > 2 months, including suspected prior treatment by another prescriber.		
	The word "Approved" should be written on prescription when prescribing dronabinol.		
	The words "Specified condition" should be written on prescriptions when prescribing psychostimulants including amphetamine, dexamphetamine, lisdexamfetamine, methylamphetamine, or methylphenidate.		
South Australia ^{11,12}	Authority from Minister for Mental Health and Substance Abuse when prescribing an S8 poison to a patient who has been treated with drugs of dependence by any prescriber for > 2 months; or before prescribing an S8 poison for drug-dependent patients.	SA Health Drugs of Dependence Unit: tel 1300 652 584	
Tasmania ¹³⁻¹⁵	Authority approval from Tasmanian Secretary for Health and Human Services (for > 2 months of treatment) before prescribing certain medicines including dexamphetamine, methylphenidate and fentanyl (for complete list, refer to Poisons Regulations 2008, reg 19); or before prescribing S8 medications to patients who are drug dependent, or who have a history of or are currently exhibiting drug-seeking behaviour.	Department of Health and Human Services Pharmaceutical Services: tel (03) 6166 0400	
Victoria ¹⁶⁻¹⁸	Permit from the Secretary (Department of Health and Human Services) before treating a drug- dependent person with an S8 drug; before treating any patient with a specifically listed S8 drug (including methadone, dexamphetamine and methylphenidate); or when treating any patient for or during a continuous period > 8 weeks with any other S8 drug.	Department of Health and Human Services: Drugs and poisons regulation in Victoria: tel 1300 364 545	
Western Australia ¹⁹	Authority approval from the Chief Executive Officer when prescribing an S8 drug for > 60 days of treatment; before prescribing an S8 drug for a patient who is drug dependent; or before prescribing flunitrazepam.	Department of Health Pharmaceutical Services Branch: tel (08) 9222 6883	

^{*} Disclaimer: The information in this table has been reviewed and approved by the relevant regulatory authority in each jurisdiction. All efforts have been taken in preparing a correct summary. However, there may be possible exceptions. For full details, refer to the relevant legislation or contact your relevant regulatory authority.

2 Current legal requirements for prescribing Schedule 8 (S8) medicines on paper script (handwritten or computer-generated) in each state and territory of Australia*

	Australian Capital Territory ⁴	New South Wales ⁵	Northern Territory ⁷	Queensland ¹⁰	South Australia ¹²	Tasmania ¹³	Victoria ^{16,17}	Western Australia ¹⁹
Prescriber								
Name	~	~	~	~	~	~	∠	~
Address	~	~	~	~	~	~	~	∠
Phone no.	~	~	∠	(only for computer- generated script)	~	х	~	(only for computer-generated script)
Qualification	~	~	~	~	X	Х	X	x
Signature	Н	Н	Н	Н	~	Н	Н	Н
Patient								
Name	/	H (for handwritten script)	~	V	1	H (with initials)	H (for handwritten script)	<i>ν</i>
		✓(for computer- generated script)					✓(for computer- generated script)	
Address	~	H (for handwritten script)	er-	ν	~	Н	H (for handwritten script)	٧
		✓(for computer- generated script)					✓(for computer- generated script)	
Date of birth	Х	x	~	~	~	Х	x	∠
Medicine								
Name	~	Н	~	H (description of the medicine)	~	Н	Н	H (description of the medicine)
Form	~	ns	~		~	ns	Н	
Strength	~	Н	~		~	ns	Н	Н
Quantity	~	H (in words and figures)	✓ (in words and figures)	H (in words and figures)	✓ (in words and figures)	Н	H (in words and figures)	Н
Direction	~	Н	~	Н	1	Н	Н	Н
No. of repeats	~	Н	~	Н	~	Н	H (in words and figures)	Н
Interval for repeats	~	Н	~	Н	Х	Н	Х	Н
Date	/	H (for handwritten script)	~	V	∠	Н	H (for handwritten script)	∠
		✓(for computer- generated script)					✓(for computer- generated script)	
Only one S8 drug per prescription	ns	~	∠	✓(different form of same S8 drug acceptable)	ns	∠	Multiple items allowed	✓ (different form of same S8 drug acceptable)

^{✓ =} required x = not required. H = information that must be written in the doctor's own handwriting. ns = not specified. * Disclaimer: The information in this table has been reviewed and approved by the relevant regulatory authority in each jurisdiction. All efforts have been taken in preparing a correct summary. For full details, refer to the relevant legislation or contact your relevant regulatory authority.

- 1 Gill A. Poisons Standard 2015. Canberra: Department of Health and Ageing, Therapeutic Goods Administration, 2015. https:// www.tga.gov.au/publication/poisons-standardsusmp#electronic (accessed Jun 2015).
- **2** Bird S. Prescribing Schedule 8 drugs. *Aust Fam Physician* 2006; 35: 59-60.
- 3 Medical Insurance Group Australia. Controlled drugs storage, documentation and destruction [fact sheet]. MIGA, 2011. http://www.miga.com.au/riskresources/library/11RRFS09.pdf (accessed Sep 2014).
- 4 Medicines, Poisons and Therapeutic Goods Regulation 2008 (ACT), regs 3, 40, 41, 556, 561. http://www.austlii.edu.au/au/legis/act/consol_reg/mpatgr2008470 (accessed Sep 2015).
- **5** Poisons and Therapeutic Goods Regulation 2008 (NSW), cll 80, 122, 123. http://www.legislation.nsw.gov.au/maintop/view/inforce/subordleg+392+2008+cd+0+N (accessed Aug 2015).
- **6** Poisons and Therapeutic Goods Act 1966 (NSW), ss 28, 29. http://www.legislation.nsw.gov.au/maintop/view/inforce/act+31+1966+cd+0+N (accessed Sep 2015).
- Medicines, Poisons and Therapeutic Goods Regulations (NT), regs 8, 10. http://www.austlii.edu.au/au/legis/nt/num_reg/mpatgr10o2014534 (accessed Sep 2015).
- 8 Medicines, Poisons and Therapeutic Goods Act 2012 (NT), ss 87, 139. http://www.austlii.edu.au/au/legis/nt/num_act/mpatga2 01213o2012425 (accessed Sep 2015).
- 9 NT Government Department of Health. Code of practice. Schedule 8 substances. Vol 1 — issuing prescriptions supplying Schedule 8 substances. 2014. http://health.nt.gov.au/library/ scripts/objectifyMedia.aspx?file=pdf/18/43.pdf&siteID=1&str_ title=Code%20of%20Practice%20S8s%20-%20Volume% 201.pdf (accessed Jul 2015).

- Health (Drugs and Poisons) Regulation 1996 (Qld), ss 79, 120. http://www5.austlii.edu.au/au/legis/qld/consol_reg/haprl 996340 (accessed Jun 2015).
- n Controlled Substances Act 1984 (SA), s 18A. http://www5.austlii.edu.au/au/legis/sa/consol_act/csa1984242 (accessed Jun 2015).
- 12 Controlled Substances (Poisons) Regulations 2011 (SA), reg 34. http://www5.austlii.edu.au/au/legis/sa/consol_reg/csr2011451 (accessed Jun 2015).
- Poisons Regulations 2008 (Tas), regs 15, 19. http://www5. austlii.edu.au/au/legis/tas/consol_reg/pr2008230 (accessed Jun 2015).
- 14 Poisons Act 1971 (Tas), s 59E. http://www.thelaw.tas.gov.au/tocview/index.w3p;cond=;doc_id=81%2B%2B1971%2BAT@EN %2B20100512100000;histon=;prompt=;rec=;term (accessed Sep 2015).
- 15 Department of Health and Human Services Pharmaceutical Branch. Important information for prescribers. Tasmanian Government, 2009. http://www.dhhs.tas.gov.au/_data/ assets/pdf_file/0004/47029/Important_information_for_ prescribers_about_legal_obligations_for_narcotic_prescribing. pdf (accessed Jun 2015).
- 16 Drugs, Poisons and Controlled Substances Regulations 2006 (Vic), reg 26. http://www5.austlii.edu.au/au/legis/vic/consol_ reg/dpacsr2006531 (accessed Jun 2015).
- 17 State Government of Victoria. Drugs and poisons regulation in Victoria. Approved by the Secretary. 16 Jun 2014. http://www.health.vic.gov.au/dpcs/approve.htm (accessed Jun 2015).
- 18 Drugs, Poisons and Controlled Substances Act 1981 (Vic), s 34. http://www.austlii.edu.au/au/legis/vic/consol_act/dpacsal 981422 (accessed Sep 2015).
- 19 Poisons Regulations 1965 (WA), regs 51, 51D, 51F. http://www5.austlii.edu.au/au/legis/wa/consol_reg/pr1965230 (accessed Jun 2015).