Online Appendix 1: Details of regulatory systems in Australia for S8 opioid analgesics for chronic non-cancer pain

Features	Tasmania	NSW	VIC	QLD	WA	SA	NT	ACT
Name	Pharmaceutical Services	Pharmaceutical Services	Drugs and Poisons Regulation	Drugs of Dependence Unit	Pharmaceutical Services	Drugs of Dependence Unit	Poisons Control	Pharmaceutical Services
Monitoring system generates alert to potential prescribing problem	Yes	No	No	Yes	Yes	Yes	Yes	No
Drug dependent patients (DDP)	Immediate authority required	Immediate authority required	Immediate authority required	Immediate authority required	Immediate authority required	Immediate authority required	Immediate authority required	Immediate authority required
Authority to prescribe needed for other patients	Yes	Yes [a]	Yes	Only notification is required	Yes	Yes	Yes [b]	Yes
Grace period before authority to prescribe required	2 months for opioids and 4 weeks for alprazolam with an opioid	2 months	8 weeks	Notification required after 2 months	60 days	2 months	60 days	2 months
Drugs applied to	Psychostimulants, all S8s opioids, Alprazolam prescribed with an opioid	Psychostimulants, hydromorphone, flunitrazepam, methadone, buprenorphine, & injectable opioids	psychostimulants and all S8 opioids	Notification required for psychostimulants and all S8 opioids	psychostimulants and all S8 opioids	psychostimulants and all S8 opioids	psychostimulants and all S8 opioids [c]	psychostimulants and all S8 opioids

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Information considered in making authority decisions	Clinical indication, risk (e.g. other drugs supplied), dose, route of administration and form, Rx contract in place, may require specialist review, escalating dose	Diagnosis, drug name, strength and form, currently drug dependent	Clinical indication; treatment plan formulated; evidence of specialist review when dose is greatly above recommended guidelines; patient notification history (drug dependence, doctor-shopping, forged prescription)	For DDP: history of dependence, genuine medical condition, signs of injecting/ doctor-shopping, urine drug screen	Diagnosis, dose and form appropriate to patient's condition, age and status (drug dependent, palliative, specialist assessment)	Treatment consistent with accepted principles of treatment of chronic pain. Relevant specialist information. Dependence history. Independent medical advice.	Clinical indication, medicine details, history of dependence, specialist assessment, palliative care status	Patient's age, clear diagnosis for which opioids are indicated, the dose and formulation, evidence of doctor-shopping, stability of dose
Legislative power to deal with prescribing breaches [d]	Can remove/ restrict S8 prescribing rights	Can remove/ restrict S8 prescribing rights	Prosecution policy in place, refer to AHPRA [c]	Can remove/ restrict S8 prescribing rights	Can remove/restrict S8 prescribing rights	Can serve prohibition order or prosecute	Can remove/ restrict S8 prescribing rights	Can refuse authority, refer to medical board, or prosecute
Internal skills employed for decision making on authorities	Pharmacists	Pharmacists	Pharmacists	Psychologist, nurse, and specialists in addiction medicine, pain, all with clinical experience in AOD[c]	Pharmacists, public health doctors	Pharmacists	Pharmacists	Pharmacists
Additional external expertise called on for decision making on authorities	GP[c] with interest in addiction medicine and pain; specialists in addiction medicine, pain.	None – all decisions made internally to the branch	Public health physician, addiction medicine specialist	GP, pharmacist, specialists in psychiatry, addiction medicine, pain.	Consultant medical specialists	Medical officer, specialists in pain, addiction medicine, psychiatry; GP.	GP, AOD nurse manager, specialists in addiction medicine, pain, palliative care, indigenous health, rural health, rehabilitation	Statutory advisory committee – psychiatrist, AMA [c] rep + 1 other (usually a GP)
Appeals by prescribers or patients	Can reapply, Informal (CHO [c], Minister) or health ombudsman		Informal and magistrate's court	Informal (CHO, Minister) or health ombudsman	Informal and State Arbitration Tribunal	Health and community services complaints commissioner, ombudsman	Nothing formal in the Act, but can write to CHO or minister. New Act will have appeals mechanism	Apply for a review to Medicines Advisory Committee within 7 days

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Possible restrictions on prescriptions	Duration, drug and dose specific. Can specify supervised dosing, restrict to single pharmacy, require specialist review	Valid for maximum 6 months	None but permits specify drug, formulation, maximum dose, permit expiry date. Advice may be included on permit for prescriber to: implement regular pick-up of medicines at 1 pharmacy, refer patient for specialist review	Limit supply (e.g. daily pickup), supervised dosing, random urine screens, review of injecting sites, reducing regimen agreed on with doctor.	Authorities issued and can be conditional on an opioid contract, limited dispensing to single pharmacy, and/or how often medication is picked up	Can specify supervised dosing, restrict to single pharmacy, require specialist review	Limit 1 month supply at a time, not allowing interstate scripts, no other restrictions on unrestricted S8s	Must specify frequency of repeats
Other details	Real time reporting and remote access to patient S8 prescribing history used to monitor and provide information to clinicians	Pharmacy and prescriber reports used to monitor prescribing	Wholesale data and pharmacy reports used to monitor geographic patterns prescribing	Formal enquiry facility for prescribers 24/7 – advice, patient history, referral options			Limit on number of patients to whom doctor can prescribe opioids	Voluntary Undertaking Scheme: links 1 doctor and pharmacy to patient

[a] authorities only required for hydromorphone, psychostimulants, flunitrazipam, injectables, but not for morphine or oxycodone.

[b] notification only is required for non-restricted S8s, authority required for restricted S8s. Refer to Note c.

[c] S8s are divided into restricted (buprenorphine, buprenorphine/naloxone, methadone and amphetamines) and non-restricted (other S8s, e.g. morphine). S4s may also be declared restricted

[d] most jurisdictions use these powers as a last resort, with prior steps including telephone calls, letters and interviews with the prescriber. It was also noted that where prescribers are having difficulties with patients using prescription opioids, they often surrender their prescribing rights voluntarily.

[e] AHPRA = Australian Health Practitioner Regulation Agency; AOD = alcohol and other drugs; GP = general practitioner; CHO = chief health officer.