



Poisons Regulations 1965 – Discussion Paper

Schedule 8 Opioid Prescribing

Introduction

The current legislation for Poisons in WA is the *Poisons Act 1964* (the Act) and the *Poisons Regulations 1965* (the Regulations). Replacement legislation in the Medicines, Poisons and Therapeutic Goods Bill 2013 (the Bill) has been presented to Parliament. If passed, the Bill will need development of subsidiary legislation to replace the Poisons Regulations 1965. Some new aspects of the Bill will need completely new Regulations to describe their operation in more detail. Many of the existing Regulations will need to be retained but may need some amendment.

The existing Regulations set out controls to protect the public from harms associated with medicines and poisons. These include restriction on supplying or using a poison, storage and disposal, packaging and labelling, record keeping and reporting, and advertising. They vary depending on the risk posed by particular medicines or poisons.

The Pharmaceutical Services Branch is consulting over the development of new subsidiary legislation and is asking stakeholders for their opinions on the existing Regulations. The Regulations can be found at: www.slp.wa.gov.au/legislation/statutes.nsf/main_mrtitle_1920_homepage.html

A specific area of the Regulations is restrictions on the prescribing of Schedule 8 drugs (S8s). This Discussion Paper has been developed to support consultation in this particular area. Although the Regulations apply to all S8 prescribing, the Discussion Paper is predominantly concerned with prescribing of opioids, such as morphine or oxycodone. It is not intended to address other agents (benzodiazepines, nabiximols), however any outcomes may also inform legislation for these drugs.

Current Regulations

Prescribing

Rules for the supply of S8s are contained in Part 6 – Drugs of addiction, Division 2 – Supply and prescription, Subdivision 2A - Supply and prescription to persons who are not drug addicts.

- prescribers need approval to prescribe S8s to a patient for more than 60 days in any 12 month period
- an approval may restrict the type of medication, amount, dispensing pharmacy, daily limit and specified repeat intervals
- prescriptions must comply with any specified conditions
- authorisations are for a specified term only
- pharmacists must comply with any specified conditions when supplying S8s
- methadone and buprenorphine (in forms not designed for treatment of addiction, e.g. patches) may only be prescribed for pain unrelated to drug addiction
- S8s can only be prescribed or supplied to an addict for medical purposes (not for treating addiction) if approved by the CEO

These rules do not apply to an inpatient while receiving care in a hospital.

Other Regulatory Programs

Other Regulations of relevance to the prescribing of Schedule 8 Drugs include:

- to supply or prescribe pharmacotherapy (methadone liquid / buprenorphine tablets) to an addict a prescriber must be authorised and follow a Community Program for Opioid Pharmacotherapy (CPOP) policies. The CEO can appoint a prescriber for an addict, for a specified period, in writing, with conditions.
- for stimulants, a prescriber must be authorised to prescribe stimulants, comply with the Stimulant Prescribing Code, and notify when treating a patient. The CEO can order a stimulant to be prescribed/supplied (or not) in a certain way

Dispensing

- prescription repeats must be retained at the pharmacy that first dispenses the prescription. These may not be transferred without the authority of the CEO.
- pharmacies must provide a monthly record of transactions to the department at the end of the month
- S8s can only be supplied without a prescription with prior personal approval of a prescriber by telephone or electronic means. A prescription must be dispatched to the pharmacy within 24 hours.
- the dispenser must verbally verify a S8 prescription with the prescriber unless he/she is familiar with the prescribers signature. If the script cannot be verified, then two days of treatment may be supplied.

Regulatory Controls

Prescribing

The Regulations listed above provide a range of controls intended to allow consumers access to S8s for legitimate medical needs, while still protecting against diversion, misuse or abuse. These rules are very similar in most States and Territories of Australia.

The key control for prescribers is that permission to prescribe S8s is required in most cases:

- for more than 60 days treatment
- for pain relief to a Registered Drug Addict
- for pharmacotherapy (for addiction) under the CPOP program
- for stimulants under the Stimulant program (note this is a *notification* system)

In each case, this has the effect of limiting one patient, to one prescriber (or practice), at any one time. Authorisation is only issued to one prescriber (or practice) at a time. If a patient moves to a new prescriber, then a new authorisation is required. If a new authorisation is issued, this cancels any prior authorisation.

Dispensing

The Regulations limit patients to supply of a S8 from one pharmacy for the life of that prescription. In addition, S8 dispensing information is provided to the Department of Health and kept on a database. This provides a complete patient history that allows identification of:

- use of multiple medical practitioners at a time
- use of multiple pharmacies (for more than one prescription)
- prescribing of multiple opioids at one time
- dose escalation
- increased dispensing or script collection frequency
- other adherence data

At present this information is collected retrospectively and is only accessible by the Department of Health. The database is regularly monitored by the Department of Health for Regulatory compliance purposes. The history for a specific patient is also used by the Department to assess and make decisions relating to issuing authorisations to prescribe.

Authorisation to Prescribe

Authorisations to prescribe are issued on behalf of the CEO by delegated Departmental Officers – generally Public Health Physicians. Decisions to approve (or not) an application to prescribe for a patient are guided by Departmental administrative rules. In 2012 these rules were reviewed and published as the “Schedule 8 Prescribing Code”. The Code can be viewed at www.public.health.wa.gov.au/cproot/4947/2/S8-medicines-prescribing-code-C20121121AG-2.pdf

The Code classifies S8 prescribing into low and high risk. Low risk includes:

- terminal illness
- over 18 years old
- dose less than 90 morphine equivalents per day (45 for immediate release preparations prescribed alone)
- slow release oral or topical dose form (or immediate release if less than 50% of daily dose)

- not a Registered Addict and no history of doctor shopping, substance abuse or diversion.

In these cases (low risk) authorities are currently issued for up to a 3 year period.

Any prescribing outside these criteria is termed high risk. Authorisation for S8 prescribing outside the criteria will only be issued with the support of a medical specialist. These authorisations require renewal annually.

All prescribing for opioids for Registered Drug Addicts is treated as high risk and requires medical specialist support for authorisation.

The authorisation system and the Code attempt to prevent the emergence of dependence. The requirement for a second opinion for high doses or injectable and immediate use products is intended as a barrier to unchecked or inappropriate use in the general setting.

At present, authorisations are granted for the drug and dose (or combination) as requested by the prescriber, without flexibility. If treatment changes, a new authorisation is required.

Current Concerns

The number of patients receiving S8 opioid medications is increasing. The number of opioid medications and formulations available is also expanding. More professional groups are now prescribing and may commence prescribing in the future. Some of these can prescribe opioid medicines. There is mounting evidence that prescribed opioids are increasingly diverted into illicit use and responsible for harm from overdose and other misuse. The overall risk to the public may then be increasing.

The number of approvals required to comply with the Regulations is increasing correspondingly. In general, the current authorisation system is not sustainable indefinitely. The current system is paper based and labour intensive.

Overall compliance by prescribers is poor. It is not uncommon for doctor shoppers or Registered Addicts to receive significant amounts of opioids.

Authorisations do represent an administrative burden for prescribers that add time and cost to treatment. Authorisations can lead to treatment delays and generate conflict between patient, prescriber and regulator.

Much current regulatory discussion in this area focuses on moving from a prospective authorisation system to a retrospective system of monitoring compliance. For example, it is suggested that there may be more value in monitoring for trends and anomalies in prescribing and intervening early to address specific patients (or prescribers) “at risk”.

The review of the Poisons Regulations provides an opportunity to review the current S8 framework. New legislation must still ensure that both patients and public are protected from risks associated with use of Schedule 8 drugs.

Issues for Discussion

This Discussion Paper will provide the basis for debate and decision in stakeholder forums on S8 prescribing. The following questions are posed to generate thought over the current regulatory controls.

Authorisation

- how does the authorisation system reduce risk to patients or the public?
- what are the disadvantages of needing to obtain authorisation to prescribe?
- how would electronic systems influence the need for an authorisation system?
- should prescribers still require authority to prescribe S8s?
- if so:
 - when should an authority be needed (is 60 days still appropriate)?
 - how long should an authorisation last before renewal is required?
 - how prescriptive should an authorisation be for drug or dose?
- how would this change if authorisations could be managed electronically?
- under what conditions might non-medical prescribers (e.g. nurse practitioners) obtain prescribing authorisation?

Prescribing Code

- how does the S8 Prescribing Code reduce risks and enhance best practice?
- what are the specific difficulties faced in complying with the Code?
- are there other ways of applying or using the Code (e.g. instead of authorisations)?
- is the current dose ceiling still appropriate?
- are there other situations that should also be considered low risk (or high risk):
 - residential care
 - specific illnesses
 - specific drugs
 - specific formulations
- is the need for specialist support (second opinion) for high risk appropriate?
- should consideration be given to peer review to support a high risk application, i.e. non-specialist?

Alternative Systems

- what systems could be used instead of authorisations?
- what are the benefits and risks of alternative systems, including:
 - no restrictions
 - notification system
 - authorisation for high risk only
 - prescriber self management (such as against a Code)
 - high risk retrospective compliance monitoring using flags in the database (against a Code)
 - combinations of above

Other Controls

- are there other non prescribing controls that could be instituted more widely, such as:
 - staged supply (daily dispensing)
 - opioid contracts
- should the CEO continue to be able to restrict individual patients to a specific medical practice or pharmacy?
- should the CEO continue to be able to restrict the medication, amount or other (e.g. repeat intervals)?
- what is an acceptable response/action taken to prescribers who continue to prescribe opioids where it is not appropriate?

Electronic Real Time Controlled Drug Reporting

The Commonwealth Government is proposing an Electronic Reporting and Recording Controlled Drug (ERRCD) system. Such a system could potentially provide real time access to the prescriber of a patient's S8 dispensing history at the time of prescribing. This system is technically feasible, but may be some time away from implementation in Western Australia. The Medicines, Poisons and Therapeutic Goods Bill 2013 contains provisions to allow the collection and sharing of these data.

- what is the responsibility of a prescriber to verify a patient history, e.g. addict status, dispensing history prior to prescribing opioids?
- when available, should use of the ERRCD system, i.e. checking, be mandatory, prior to prescribing a S8?
- what is appropriate action against prescribers refusing to use the system or prescribe when the ERRCD shows it is inappropriate?
- does real time information change the need for an authorisation system?
- which alternative system to authorisations would work best with ERRCD?
- how could the ERRCD system be used to restrict a patient to one doctor and one pharmacy?

Other Prescribers

Nurse practitioners are already able to prescribe S8 medications in WA. At present a nurse practitioner must be designated and provide clinical protocols to the Department of Health. These restrictions are not likely to transition in to new Regulations.

To date S8 prescribing by this group appears to be part of collaborative care, is generally continuation of that commenced by a medical practitioner, or restricted to specialised areas such as palliative care. This may not be the case in the future.

- what specific controls should apply to S8 prescribing or authorisation of prescribing for this group (or other new groups)?
- should the controls be different (more stringent) to those for medical practitioners?

Other Considerations

- are the existing controls at the point of dispensing adequate?
- are there other ways to reduce risks of opioid misuse at the pharmacy level?
- how can S8 prescriptions be better protected against forgery or fraud (for example requiring addition of authorisation numbers)?
- how will use of electronic prescriptions (issued over the internet in script exchanges) affect the need for these controls?

Drug Dependent Persons

Under the Bill, the current Register of Drug Addicts would be reformed. However, as the Bill proposes that drug dependent persons are still notified, it is likely that prescribing restrictions for this group would be retained. The notification of a drug dependent person will remain the responsibility of the treating clinician based on the basis of their professional assessment of dependency.

Oversupplied Persons

The Bill does allow the Department to form a view that a patient may be over supplied. This might for example apply to persons attending multiple practitioners concurrently or receiving amounts over time that are well in excess of personal needs based on the prescribed dosage. An oversupplied person may be subject to controls, such as an authorisation system, similar to that of a drug dependent person.

Regulatory Options

The status quo, where authorisations are required for all prescribing, is no longer considered feasible. The need for authorisation of all opioid prescribing is the highest level of regulatory control and attempts to protect public health more widely by influencing prescribing at initiation of opiate therapy. It provides very limited prescribing freedom. As the current system suffers from many disadvantages, it is not an option being considered.

The removal of all prescribing restrictions would mean public protection must rely on other regulatory controls or other legislation. As few controls on opioid prescribing exist outside Poisons legislation there would be limited ability of the Department to respond to and intervene on issues of individual or public safety with opiate prescribing. This is also inconsistent with the approaches in all other Australian jurisdictions.

Several viable options have been identified that could provide varying levels of public protection and may address failings of the current Regulations. These four options are outlined below from least restrictive to most restrictive.

It should be noted that all options proposed will need a set of agreed best practice rules to function. The current S8 Prescribing Code might be modified and adopted to provide these rules. This Code may need to be referenced in regulations. The Code would need to set out the criteria for prescribing, where Department interaction is required and when additional regulatory controls are to be exercised.

Option 1

- prescriber self regulation according a Schedule 8 Prescribing Code

Option 1 would remove the need for prior authorisation for opioid prescribing. A published Code would be used to set limits and describe practices that are acceptable.

Option 1 allows prescribers to self regulate and would remove administrative requirements. The Code would serve as the control. This option assumes that the majority of prescribers will self-manage appropriately and this is sufficient public protection.

Prescribers would need to be aware of and comply with the Code. The Code would need to contain sufficient detail on acceptable prescribing behaviour for all situations. For example: how a prescriber may prescribe opioids to a person with a history of drug dependence.

This option would require the Department to be able to monitor prescribing and take action where prescribing falls outside the Code. Mostly this might involve review of information on medication supplies provided by community pharmacies, however the Department may need to conduct audits or other activities to determine prescriber compliance.

Monitoring would be linked to reactive measures for behaviour of concern. In these cases the CEO may need to retain the right to direct that a practitioner prescribe in a certain way or remove prescribing rights for gross non-compliance.

Option 2

- prescribing authorities for high risk Schedule 8 prescribing only

Option 2 would require a Code to set out criteria for low risk and high risk prescribing. Within the low risk criteria practitioners could self manage without needing prior authorisation to prescribe.

For high risk prescribing, such as very high doses, prior authorisation would be required. It is expected an approval would be contingent on medical specialist support or some other similar higher level control.

Option 2 would remove the majority of administrative burden on prescribers. This option provides public protection, targeted at specific predetermined risk areas.

This option would only focus on high risk prescribing. It assumes that the majority of risk from opioid prescribing is manageable by individual practitioners and does not require monitoring by the Department.

Monitoring would occur, but would be targeted towards compliance with high risk authorisation requirements, and identifying patients or prescribing patterns indicating high risk.

Option 2 is the preferred option of the Department of Health.

Option 3

- notification (flexible) for low risk and authorisation for high risk

Option 3 proposes notifications for low risk prescribing according to criteria set out in the Code. For high risk prescribing, prior authorisation would be required as in Option 2.

A notification is a written notice of intent to commence prescribing, submitted at the time of issuing the first prescription. It would need to include basic information on patient, diagnosis and medication prescribed to allow assessment against low risk criteria. Prescribing could commence immediately as a positive approval is not required.

In option 3, notification would be flexible and allow for modification of both drug and dose as long as remaining within the low risk criteria. A notification is not time limited. This means only one notification is required for the entire duration of low risk treatment. If a patient moves to a new practitioner (practice) re-notification would be necessary.

Option 3 is less intensive than the current authorisation system, but still requires administrative effort by practitioners to provide notification for all opioid prescribing.

The benefit of a notification is to allow a patient to be assigned as being treated by one primary practitioner (or practice). This allows for other practitioners to know there is already a primary prescriber and for the Department to monitor and respond to significant movement between practitioners or existence of multiple prescribers at once.

Option 4

- notification (rigid) for low risk and authorisation for high risk

Option 4 is an extension of Option 3. It would employ notification for low risk and authorisation for high risk.

The notification system would be less flexible than in option 3. The practitioner would nominate a specific drug and dose. When the drug or dose changed a re-notification would be required. This model is very similar to the current program used for stimulant prescribing.

This option would require the submission of notifications and re-notifications. This is still less onerous than the current authorisation system as no positive approval is required and prescribing could commence immediately.

This option provides the ability to monitor actual prescribing from community pharmacy supply data against the intended prescribing as contained in notification data.