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Ms Lidia Lo Giusto
Coroner's Registrar
Coroners Court of Victoria
Level 11, 222 Exhibition Street
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Dear Ms Lo Giusto

Court Reference: 4042/08 David Trengrove

I am writing in response to your letter dated 28 May 2012 in relation to the recommendations made by Coroner Audrey Jamieson in the above case.

Coroner Jamieson has referred to a finding made by Coroner Olle in the death of James (Court ref: 5181/09) as both deaths were a result of mixed drug toxicity obtained through prescription shopping. I again acknowledge the serious issues that David's death, as well as other deaths including James and Rory (Court ref: 4232/10) bring to light on the complexities of prescription drug misuse. My department continues its work on the national policy response to this developing public health issue.

My responses are as follows:

Recommendation:

1. The Victorian Department of Health implement a real-time prescription monitoring system within 12 month, in order to reduce deaths and harm associated with prescription shopping. The system should be implemented in such a way that it is readily accessible via the internet to Victorian prescribers and dispensers during consultations, so they can check patients' histories and therefore make informed prescribing and dispensing decisions 'on the spot'.

The department's response:

My department continues to engage with the Commonwealth on its development of a national real-time prescription monitoring system through its Electronic Recording and Reporting of Controlled Drugs (ERRCD) initiative. While the Commonwealth intends to deliver the system which is already in operation in Tasmania, there is significant detail to be worked through to ensure that the Tasmanian system can be implemented nationally. While not an exhaustive list, such matters include ensuring that appropriate protection of individuals' health information is in place, ensuring that interfacing with a broad range of both public and private sector software systems can occur and fundamentally ensuring that the Tasmanian system is robust enough to scale up to a level which will have exponentially more data moving through it. I raise these matters to highlight that implementing software that is already functioning in Tasmania is not a straight-forward process and while it is a priority, it must be afforded thorough consideration to ensure it is implemented successfully.

The Coroner recommends that the Commonwealth's ERRCD system include functionality for prescribers and dispensers to access patient histories 'on the spot' during patient consultations. While I cannot speak on behalf of the Commonwealth on the functional components of its software, I can provide a fact sheet prepared by the Commonwealth on the ERRCD initiative which includes some details on how the system is intended to operate (see attached). I refer to the following text under the heading 'How the system will work':

> "During a clinical interaction, authorised prescribers and pharmacists may access data on a consumer via a secure web portal that may help to inform their clinical decision-making. The ability of prescribers and pharmacists to view the history of Controlled Drugs that have been dispensed to a consumer will be a key feature of the system."

Recommendation:

5. That Drugs and Poisons Regulation at the Victorian Department of Health consider introducing a requirement that where a practitioner prescribes a Schedule 8 poison to treat chronic non-malignant pain on a long-term basis, the practitioner must submit evidence that the patient has been periodically reviewed by a pain specialist to support the ongoing treatment. The purpose of this recommendation is to ensure that patients treated for chronic non-malignant pain receive expert evidence-based care, thus reducing their inappropriate exposure to Schedule 8 poisons and the associated risk of harm and death.

The department's response:

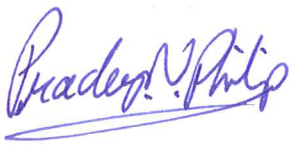
The Coroner makes reference to my department's policy which advises medical practitioners on requirements for approving applications for Schedule 8 permits (see attached). The policy references National Prescribing Service (NPS) recommendations on the use of opioids in chronic non-malignant pain, including the recommendation that a maximum daily dose equivalent to 120mg of morphine should not be exceeded without obtaining specialist advice as the risks of problematic use and potential harms at higher doses outweigh the potential analgesic benefit of opioids. The NPS does not recommend that routine specialist advice be sought for chronic pain relief at lesser doses.

Applications for Schedule 8 permits are assessed on a case-by-case basis. While the issue of a Schedule 8 permit is not an endorsement of treatment, the policy clearly states that in assessing applications to prescribe opioids on a long-term basis, the department may refuse to issue a permit if there is no evidence of specialist support for treatment with doses higher than the maximum doses recommended by the NPS.

In my view, the procedures that the department has in place as outlined in the policy are consistent with the Coroner's recommendation while also taking into account current best practice advice from the NPS. The policy is publically available on the department's website and practitioners are routinely referred to this document when their applications are processed by my department.

If you require further information please contact Mr Matthew McCrone, Chief Officer, Drugs and Poisons Regulation on 9096 5066 or email matthew.mccrone@health.vic.gov.au.

Yours sincerely



Dr Pradeep Philip
Secretary

Encl.
Attachment 1 – Commonwealth ERRCD fact sheet
Attachment 2 – *Policy for the issue of permits to prescribe Schedule 8 poisons*

Electronic Recording and Reporting of Controlled Drugs

Context

Current regulations for Controlled Drugs (i.e. 'Dangerous' or 'Schedule 8' Drugs) are set out in relevant State and Territory medicines and poisons legislation. Common across all jurisdictions is a requirement of the pharmacist to record transactions for all Controlled Drugs in a register. Some jurisdictions also require regular reporting of all supplies by the pharmacy to the state or territory health department. The monitoring of compliance by these jurisdictions and the investigation of issues such as inappropriate use or prescribing by more than one doctor/practice to a consumer is all significantly dependent on the receipt of dispensing reports from pharmacies. Manual recording and non-real time reporting mechanisms slow this process down and are open to errors and omissions.

A move from manual to electronic recording and real-time reporting will improve the ability to efficiently monitor the prescribing and dispensing of Controlled Drugs to ensure appropriate access to these medicines. Real-time access to accurate dispensing information will improve the efficiency by which state and territory regulators, prescribers and pharmacists identify problems of forgery, abuse and doctor shopping and improve public health outcomes. Electronic recording will improve the accuracy and efficiency for pharmacists when recording transactions of Controlled Drugs .

The Fifth Community Pharmacy Agreement (Fifth Agreement) between the Australian Government and The Pharmacy Guild of Australia commenced on 1 July 2010. It is a five year agreement that recognises the important part that is played by community pharmacy in primary health care.

The Electronic Recording and Reporting of Controlled Drugs (ERRCD) initiative is one of the initiatives to be implemented under the Fifth Agreement. It aims to develop a nationally consistent system to collect and report data relating to the dispensing of Controlled Drugs which will complement and support the current regulatory controls required by states and territories.

Description

The Electronic Recording and Reporting of Controlled Drugs (ERRCD) initiative will see the development and implementation of software programs that will provide:

- a nationally consistent Controlled Drug Electronic Register;
- a nationally consistent electronic system to collect and report data relating to the dispensing of Controlled Drugs; and
- real-time access for prescribers and pharmacists to current information on dispensing events for Controlled Drugs.

On 12 February 2012, the Minister for Health, the Hon Tanya Plibersek MP, announced that a licensing agreement had been signed with the Tasmanian Department of Health and Human Services to use their existing Controlled Drugs monitoring system as the platform for the nationalised ERRCD system to be made available to all states and territories .

The ERRCD system will help enable prescribers, pharmacists and state and territory regulators across Australia to more effectively and efficiently monitor the use of these medicines.

What the system will do

The ERRCD system will collect information on all dispensing events related to Controlled Drugs consistent with state and territory legislation.

The system provides a source of data for prescribers, pharmacists and state and territory regulators about the dispensing of Controlled Drugs. This data will include information relating to the person who has been dispensed a Controlled Drug such as name, date of birth, as well as information on the medicine dispensed such as strength, form and date of dispensing.

In contrast to e-Health developments, the ERRCD system will not be an 'opt-in' system such as that proposed for the Personally Controlled Electronic Health Record.

How the system will work

The system will comprise of a number of components, some of which will be internet based. It will provide a web portal for both prescribers and pharmacists, and will integrate with pharmacy dispensing systems to capture information relating to the provision of Controlled Drugs.

The system will provide the capacity for state and territory regulators to access recorded information through a secure web interface allowing them to manage the system, and respond as required, to alerts that have been raised by the system.

During a clinical interaction, authorised prescribers and pharmacists may access data on a consumer via a secure web portal that may help to inform their clinical decision-making. The ability of prescribers and pharmacists to view the history of Controlled Drugs that have been dispensed to a consumer will be a key feature of the system.

[1] www.health.gov.au/internet/ministers/publishing.nsf/Content/183A5624EC33E96FCA2579A400767F54/$File/TP014.pdf

Australian Government
Department of Health and Ageing

The Pharmacy Guild of Australia

The Electronic Recording and Reporting of Controlled Drugs initiative is funded by the Australian Government Department of Health and Ageing as part of the Fifth Community Pharmacy Agreement between the Commonwealth and The Pharmacy Guild of Australia

Protecting privacy

There are stringent laws in place regulating to the handling of personal health data. The ERRCD system will comply with relevant standards for security of electronic and personal health data to a level compatible with PROTECTED data in accordance with the Australian Government Protective Security Policy Framework.

Implementation date

The electronic system to collect and report dispensing data relating to Controlled Drugs will be made available to State and Territory regulators from July 2012.

Given that regulations for Controlled Drugs are contained within State and Territory statutory rules, the implementation of this initiative will require amendments to these statutory rules in order to allow prescribers and dispensers to access information. The system will also need to integrate with existing state and territory information and communication technologies and processes. This will see some variation of the date between jurisdictions that the system becomes available for use.

Medicines included in this initiative

All medicines included in Schedule 8 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) which is given legal effect through state and territory legislation will be monitored by the ERRCD system. Schedule 8 of the SUSMP includes substances which should be available for use but require restriction in their manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence. In addition to Schedule 8 medicines, individual states and territories may use the ERRCD system to monitor other medicines that may be subject to jurisdictional regulatory arrangements.

All Controlled Drugs, whether they are dispensed as Pharmaceutical Benefits Scheme (PBS) or non-PBS (private) prescriptions, will be reported by the system.

Maintaining legitimate use of Controlled Drugs

The initiative is not intended to present a barrier to access for legitimate use of Controlled Drugs, such as consumers with severe chronic disabling pain or those receiving palliative care.

The ERRCD system will contain functions that allow authorised state and territory regulators to perform activities such as processing prescribing approvals for Controlled Drugs and managing Controlled Drug records. The system will allow regulators to determine breach conditions and set pre-defined criteria that will alert them to particular prescribing and dispensing activities that suggest forgery, abuse or doctor shopping. The breach alerts could be set to exclude dispensing events for particular consumer groups, such as palliative care patients.

Changes to prescribing and dispensing software

An interface between prescribing software and the ERRCD system is required so that prescribers can access the system from their prescribing software. Pharmacy dispensing software will be upgraded to facilitate integration with the ERRCD system.

Replacement of paper-based Controlled Drugs registers

Currently, it is a legislative requirement in all states and territories for all pharmacies along with other persons/facilities able to possess these substances, to record all transactions of Controlled Drugs. This register must also show the balance of Controlled Drugs on hand. This is in addition to the current arrangements of some states and territories where pharmacists are required to report the dispensing of a Controlled Drug by periodically sending prescription duplicates or records to their state or territory department of health.

This initiative will see the development of an Controlled Drug Electronic Register (CDER) that interfaces with existing pharmacy dispensing software. This function will assist pharmacists to efficiently meet their statutory obligations to maintain records of Controlled Drugs.

Although there are no national uniform regulations in place specifying the requirements for a CDER, the Commonwealth and The Pharmacy Guild of Australia will work closely with state and territory regulators to ensure that the CDER meets jurisdictional requirements and can be used in place of a paper-based Controlled Drugs register. This component of the initiative will be introduced separately to the reporting of dispensing events.

[2] www.ag.gov.au/Protectivesecuritypolicyframework/Pages/default.aspx
[3] www.tga.gov.au/industry/scheduling-poisons-standard.htm

Policy for the issue of permits to prescribe Schedule 8 poisons

health

May 2011

Introduction

The Victorian Drugs, Poisons and Controlled Substances (DPCS) legislation sets out certain circumstances when a medical practitioner or nurse practitioner must obtain a permit to prescribe a Schedule 8 poison (S8).[1,2] These are substances which should be available for use but require restrictions on supply to minimise abuse, misuse and dependence.[3]

Generally a permit is required for any treatment of a drug dependent person, treatment with a S8 for more than eight weeks (including any period of treatment provided by another practitioner), or any treatment with methadone, dexamphetamine or methylphenidate. There are exceptions to these general obligations however. It is the responsibility of the practitioner to know if they are required by the legislation to hold a permit in a particular case.

This document sets out the policies of the Drugs and Poisons Regulation Group (DPRG) when assessing an application from a practitioner for a permit to prescribe a S8. Information about a practitioner's obligations under the legislation, including downloadable copies of this and other departmental policies and other information about drugs and poisons controls in Victoria can be obtained by calling the DPRG on 1300 364 545, or from the DPRG website at www.health.vic.gov.au/dpu. The department has also developed advice sheets concerning different aspects of treatment with S8s, including recognising behaviours indicative of substance abuse. These advice sheets can also be obtained from the DPRG website.

The role of the DPRG

The requirement for a permit recognises the special risks associated with S8s, and the consequent need to coordinate treatments between practitioners to minimise these risks to patients. The requirement for a permit for treatment with a S8 assists to coordinate treatment and minimise the risk of concurrent treatment of a patient with the same or similar S8 by different practitioners. The department is not in a position to make clinical judgments in a particular case and does not offer clinical advice to a practitioner. The issue of a permit by the department is not an endorsement of treatment. The responsibility for assessing the appropriateness of treatment of a patient rests with the applicant practitioner in a particular case.

On receiving an application for a permit to prescribe, the DPRG accesses a database which has a history of current or past permits, notifications of drug dependency and other information obtained from medical practitioners, pharmacists and other health practitioners. Some of this information may be relevant to the current applicant and is normally provided to assist the applicant to make legal, safe and effective treatment decisions.

The DPRG is also aware of certain relevant references and clinical guidelines, such as the Therapeutic Guidelines (TG), the Australian Medicines Handbook (AMH), the Australian Pain Society (APS), and the National Prescribing Service (NPS).

The DPRG has access to departmental medical officers and experts in the field of treatment of conditions where S8s are prescribed and in treatment of drug dependent patients. These, and other points of reference, have assisted the department to develop policies that guide the processing of applications to prescribe, and the decision to issue or revoke a permit, or to refuse an application.

The overriding goal at all times is to maximise patient safety and to minimise the risks of developing or maintaining dependence or the diversion of licit drugs for illicit purposes. The policies described below indicate the position the DPRG will generally adopt when an application is

received. Applicants are encouraged to contact the DPRG on 1300 364 545 to discuss a particular case with a Drugs and Poisons Officer if necessary.

Specific policies

1. Relevant history

Normally the clinical judgment of the practitioner will be accepted when assessing applications. Where an application is received and:-

i. the drug is indicated for the specified diagnosis for that patient, and
ii. is within the normal therapeutic dose range, and
iii. there is no history of previous permits or notifications,

the permit will generally be issued with no further contact with the applicant.

Where the DPRG has information about past permits or notification of drug dependency for that patient or other information that might be relevant to the current application and the applicant may not be aware of, this information is normally conveyed to the applicant. The applicant will be given the opportunity to consider the proposed treatment in light of this information.

Where there is:-

i. a current, active permit in place for either the same or a different S8, or
ii. a history of permits for opioid replacement therapy (ORT), or
iii. notifications of drug dependence or suspected unlawful behaviour associated with prescription medications, or
iv. concern about an aspect of the application that may compromise the safety of the patient,

the practitioner will normally be contacted. Before a permit is issued in these cases, the DPRG will seek from the applicant sufficient information to demonstrate that adequate consultation with colleagues has occurred to give confidence co-ordinated and safe treatment will be delivered. Applications may be refused if the additional information requested is not provided.

Generally, a permit for the same drug or similar will not be issued to more than one practitioner concurrently unless it is clear to the DPRG that adequate communication between the practitioners has occurred and ongoing treatment will be co-ordinated.

2. Incomplete applications

The DPCS Regulations 2006 stipulate the information that must be provided when applying for a permit to prescribe a S8. Applications may be processed only if the information required by the legislation is supplied by the applicant. It is not appropriate for the DPRG to obtain information on behalf of applicants.

When an incomplete application is received the applicant will be asked to provide the information required to complete the application. The processing of the application will be suspended until either:-

i. the applicant provides the required information and the processing of the application can proceed, or
ii. 10 working days elapse and the required information has not been received. In this case the applicant will be advised that the application has not been processed. A new application will be necessary if the permit is still required.

It should be noted that it is an offence to deliberately provide false information in relation to an application for a permit (see section 49 of DPCS Act 1981).

In the case of ORT applications, the department considers it essential for the safe treatment of patients transferring from one practitioner to another that the drug, dose and date of last dose be obtained by direct contact with the most recent dosing point. Where possible the previous practitioner should also be contacted by the applicant to be advised that the patient has transferred, and to seek any relevant information that may assist with treatment.

3. Applications to treat pain with opioids

Before prescribing opioids

The TG state that starting opioids is not a trivial decision, and opioids should not be commenced unless the practitioner knows the patient and understands their psychosocial situation.[4] The APS advises that it is essential that all reasonable attempts be made to achieve a diagnosis for the cause of the pain, including nociceptive, neuropathic and psychological contributions.[5]

It is important that practitioners know how to recognise problematic behaviour that is

symptomatic of substance abuse disorder, and be equipped to manage it when prescribing opioids.

The NPS advises that a pain management plan should be formulated and discussed with the patient before deciding to prescribe opioids.[6] This should include defining the goals of therapy, setting an appropriate treatment timeframe, establishing a review process with colleagues or a specialist to regularly assess treatment outcomes and appropriateness of ongoing treatment, and informing the patient of his/her responsibilities to adhere to the treatment plan.

The DPRG would expect applicants to have formulated a pain management plan when deciding to prescribe opioids. Further, the DPRG may request confirmation that a pain management plan has been formulated when assessing an application. Failure to provide confirmation of a pain management plan may result in an application being refused.

Concurrent prescribing

The APS advises that it is important that only one practitioner prescribes opioids for a patient and assesses the response.[5] Where a current permit is held by another practitioner the applicant will be advised to make contact with that permit holder to coordinate treatment. Generally concurrent permits will not be issued. An exception might be made where there is close cooperation between practitioners. If more than one permit is to be issued, it is the responsibility of the applicant to demonstrate that adequate consultation and coordination will be in place during the period of treatment.

Long term use

The APS advises that all patients who are considered for long term use of opioids in non-malignant pain should be assessed at some stage in a specialist pain management centre. Further, stable patients should be reviewed annually, otherwise more frequent assessments will be necessary. The prescribing doctor should review monthly.[5]

The NPS advises that specialist advice should be sought for patients requiring repeated dose escalations or higher doses of opioids.[6] The NPS also refers to the Hunter New England Area Health Service dose recommendations (see Table 1) for suggested maximum opioid doses that should not be exceeded without specialist advice.

Table 1: Suggested maximum opioid doses[7]

Generic name	Suggested maximum dose
hydromorphone	24mg daily
methadone	40mg daily
morphine	120mg daily
oxycodone	80mg daily
buprenorphine patch	40mcg/hr weekly
fentanyl patch	25mcg/hr every three days

Because of the department's role in minimising the risk of dependence, clarification may be sought from applicants about the level of specialist support they have obtained when considering long term opioid treatment.

Applications for higher doses of opioids (i.e. significantly above the suggested maximum dose) will generally require evidence that recent supportive advice has been obtained from a specialist for a permit to be issued. Without such evidence, applications may be refused.

Opioid treatment in patients with previous ORT permits or notifications

The TG provide advice to practitioners about the use of opioid analgesics in opioid dependent patients or patients with substance misuse disorder. The TG advise that due to the difficulties of treating opioid dependent patients with opioids, early advice from a pain or addiction medicine specialist may be required. The TG advise that patients recovering from opioid dependence pose additional problems, and that regular assessment of treatment, as well as coordination with the patient's drug treatment team and carers is advised.[4]

A history of drug dependence does not preclude the use of opioids to treat pain, but it is advisable that practitioners should have consulted a specialist in addiction medicine and that a detailed pain management plan for the patient has been formulated before deciding on treatment.

Applications to treat patients with a history of drug dependency will generally require evidence that recent supportive advice has been obtained from a specialist for a permit to be issued. Without such evidence, applications may be refused.

Codeine for chronic pain

The NPS advises that codeine has a limited role in the treatment of chronic pain, and is a short-acting opioid suitable only for mild to moderate pain.[6] The AMH states that the maximum daily dose of

codeine is 240mg daily, and advises that an alternative opioid should be considered if this dose is reached.[8]

Applications for doses of codeine greater than 240mg daily will generally require evidence that recent supportive advice has been obtained from a specialist for a permit to be issued. Without such evidence, applications may be refused.

Injectable opioids for chronic pain

The APS advises that: *"There is agreement internationally and within Australia that intra-muscular opioids should play no part in the treatment of chronic nonmalignant pain. In particular intra-muscular pethidine should be avoided".*[5]

Sustained release oral or transdermal opioid preparations are the drugs of choice in patients with chronic non-malignant pain, because of their single or twice daily dosage and stable blood concentrations as a consequence of their more predictable pharmacokinetics.[5,6]

Applications for use of injectable opioids will generally require evidence that recent supportive advice has been obtained from a specialist for a permit to be issued. Without such evidence, applications may be refused.

4. Applications for dexamphetamine or methylphenidate

Attention Deficit Hyperactivity Disorder

The legislation provides for an exemption from the requirement for a permit for practitioners treating Attention Deficit Hyperactivity Disorder (ADHD) with dexamphetamine or methylphenidate where the patient is under the age of 18 years and the treating practitioner is a paediatrician or a psychiatrist.

In these cases the treating practitioner must make a notification of treatment (a section 34D notification) by completing Section 3 of the S8 permit application form. The section 34D exemption from holding a permit does not apply to adult ADHD patients. The department takes the view, however, that specialist involvement in treatment is necessary for ongoing management of all ADHD patients.

General Practitioners (GP) will generally not be issued with a permit for dexamphetamine or methylphenidate unless the application indicates that there is evidence of a specialist diagnosis and at least yearly reviews by a specialist.

Narcolepsy

The department has established a policy that an initial diagnosis of narcolepsy must involve a respiratory physician or a specialist in sleep disorders. A GP will generally not be issued with a permit for dexamphetamine or methylphenidate unless the application indicates that a specialist has been consulted and endorses the treatment.

The department considers that, once narcolepsy is diagnosed, ongoing treatment by the GP is generally appropriate without further reference to a specialist, provided other risks to patient safety are not evident.

Other conditions

Provided there is documented evidence for its therapeutic use, permits to treat other conditions with dexamphetamine and methylphenidate will generally only be issued to specialists.

GPs will generally not be issued with a permit unless the application indicates that there is evidence of a specialist diagnosis and at least yearly reviews by a specialist.

5. Applications for flunitrazepam

The AMH states that flunitrazepam is not recommended for initial drug treatment of insomnia or anxiety and misuse of the drug is common.[8]

The TG advise that hypnotics should only be used in the treatment of insomnia for the shortest time possible (preferably intermittently and for less than two weeks) and a definite duration of use agreed with the patient at the outset.[9] Continuous long-term use of flunitrazepam is not recommended.[10]

Applications for flunitrazepam will generally require evidence that recent supportive advice has been obtained from a specialist in sleep disorders or a psychiatrist for a permit to be issued. Without such evidence, applications may be refused.

6. Applications to prescribe S8 to treat drug dependence

The use of agonist replacement therapies has been used to treat drug dependence. In the case of opioid dependence, an extensive evidence base exists for replacement therapy with methadone or buprenorphine. The department provides extensive advice to practitioners in its *Policy for Maintenance Pharmacotherapy for Opioid Dependence*. This policy is available on request from the DPRG website at www.health.vic.gov.au/dpu.

The DPRG website also contains links to the national clinical guidelines for methadone and buprenorphine.

Replacement therapy for opioid dependence is a field that carries with it particular risks requiring either adequate training or supervision of treatment. Generally permits will only be issued to practitioners who:-

i. have successfully completed recognised training and a test of competency, or
ii. are treating under the supervision of, or in a shared care arrangement with, a trained practitioner.

Practitioners wishing to be authorised to prescribe opioid replacement therapy should contact the DPRG on 1300 364 545.

Expert advice indicates that the evidence base for any other replacement therapies for drug dependence is inadequate. Generally permits to treat drug dependence, other than for the treatment of opioid dependence with methadone or buprenorphine, will not be issued.

Applicants may contact the DPRG to discuss particular cases but are advised that evidence should be provided that an expert in addiction medicine has endorsed the treatment, or that the treatment is part of a clinical trial with ethics approval.

7. Applications for treatment outside normal medical practice

Permits for the use of S8s where there is a limited evidence base, or outside common medical practice will generally not be issued unless supported by expert opinion, or as part of a clinical trial with ethics approval.

References: 1. Drugs, Poisons and Controlled Substances Act 1981. 2. Drugs, Poisons and Controlled Substances Regulations 2006. 3. Standard for the Uniform Scheduling of Medicines and Poisons No. 1 (2010). 4. Therapeutic Guidelines: Analgesic (2007). 5. Graziotti PJ, Goucke CR. The use of oral opioids in patients with chronic non-cancer pain: Management strategies. Med J Aust (1997); 167:30-4. 6. National Prescribing Service. NPS News 69: A planned approach to prescribing opioids (2010). 7. Hunter New England NSW Health. Pain matters: Opioids in persistent pain (2010). 8. Australian Medicines Handbook (2011). 9. Therapeutic Guidelines: Psychotropic (2008). 10. MIMS Annual. Hypnodorm Full Product Information (2010).