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Investigation into the administration of s59E of the *Poisons Act 1971* by the Pharmaceutical Services Branch of the Department of Health and Human Services

March 2013

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ABBREVIATIONS AND ACRONYMS

ADDA	Alcohol and Drug Dependency Act 1968
ADS	Alcohol and Drug Service
AHPRA	Australian Health Practitioners Regulation Agency
AHMAC	Australian Health Minister's Advisory Council
CMO	Consulting Medical Officer
DAPIS	Drugs and Poisons Information System
DHHS	Department of Health and Human Services
DORA	Drugs Online Remote Access
EAP	Expert Advisory Panel
ERRCD	Electronic Recording and Reporting of Controlled Drugs
GP	General Practitioner
mg	Milligram
NCETA	National Centre for Education and Training on Addiction
NDARC	National Drug and Alcohol Research Centre
PSB	Pharmaceutical Services Branch
RACGP	Royal Australian College of General Practitioners
RANZCP	Royal Australian and New Zealand College of Psychiatrists
RHH	Royal Hobart Hospital
S8	Schedule 8 of the Uniform Standard[1]
S4	Schedule 4 of the Uniform Standard [2]
The Act	Poisons Act 1971
The Minister	The Minister for Health
The Secretary	The Secretary of the Department of Health and Human Services
TOPP	Tasmanian Opioid Pharmacotherapy Program Policy and Clinical Practice Standards

[1] Being substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence (e.g. opioid drugs such as oxycodone).

[2] Being substances which are available from a pharmacist on prescription (e.g. benzodiazepine and drugs such as alprazolam).

EXECUTIVE SUMMARY

In 2007 my Office received a complaint about a decision of the Pharmaceutical Services Branch of the Department of Health and Human Services. By 2011 over 50 similar complaints had been received. All were from patients affected by decisions of PSB authorising medical practitioners to prescribe Schedule 8 drugs, primarily opioid analgesics.

Nearly all the complainants had been receiving long-term pain medication for medical problems and they asserted that:

- the amount of drugs that could be prescribed to them had changed; or
- the type of drug that could be prescribed had changed; or
- changes had been made to the frequency or location for pickup of these drugs.

The complainants alleged that they were:

- no longer getting adequate pain relief; and/or
- incurring increased dispensing or travel costs as a result of limitations placed on the amount of medication that could be dispensed to them at any one time; and/or
- experiencing increased inconvenience or distress.

A recurring feature of the complaints was that the complainants appeared to have little or no knowledge of the basis for the decisions that had been made to alter their medication regimes. They also complained that there was no one to whom they could take their concerns, apart from my Office, because no one from PSB would talk to them.

My predecessor commenced an own motion investigation in March 2011, because the number of complaints received raised concerns as to whether the legislation was being correctly and reasonably administered, and as to whether the Department had reasonable channels of communication open for people affected by its decisions. I note here that the purpose of the investigation was to look at whether the legislation was being appropriately administered and was not concerned with any clinical decisions.

The terms of reference for the investigation focused on the administration of s 59E of the *Poisons Act 1971,* the legislation which, since 2009, has controlled the availability of narcotic substances through medical practitioners to their patients. Sections 20 and 22 of the *Alcohol and Drug Dependency Act 1968* fulfilled this task until they were repealed in 2009, and some of the earlier complaints were in relation to those sections. My investigation, however, was focused principally on the administration of s 59E.

In brief, s 59E empowers the Secretary of the Department, on the application of a medical practitioner, to authorise the practitioner to prescribe a Schedule 8 drug for

the use of a particular named patient. In practice, the Secretary delegates decisions on such applications to PSB's pharmacists.

When a medical practitioner applies for authorisation, the PSB pharmacist/delegate can decide either to authorise the prescription of the drug requested to the particular patient, refuse to authorise its prescription, or authorise it subject to conditions.

Authorisation may include one or more of the following conditions:

- the prescription is to be lodged with one nominated pharmacy;
- the drugs are to be dispensed weekly, twice-weekly, thrice weekly, daily, or daily under supervision from the pharmacy;
- the patient is to see a specialist within a specified time;
- a drug different to that requested is to be dispensed;
- a lesser quantity of the requested drug is to be dispensed; and/or
- the drug is only authorised for a short time.

In order to investigate the reasonableness of the decisions being made by PSB, it was necessary for my investigator first of all to become familiar with the complex real-time reporting database PSB had just introduced. This database has made PSB, in effect, a paperless office and therefore any investigation would have been difficult if not impossible without having access to it. For that purpose, my investigator spent three weeks at PSB, during which time she was able to navigate the database and to observe the decision-making practices of the pharmacist/delegates.

Summary of Conclusions and Recommendations

In my view, there are no serious shortcomings in the way that s 59E is administered by PSB. As with any agency, there are some areas which could be improved, and PSB has responded positively to my suggestions and recommendations in this regard. This illustrates that a review by an independent and impartial auditor can be a productive process, bringing benefits not only to an agency but promoting good administration generally.

I also acknowledge that PSB carries out its work in relation to s 59E in a difficult environment, with sometimes difficult patients; with limited resources, and responsibility for administering the Poisons Act as a whole. Its ability to administer the section has been greatly enhanced by the introduction of the DAPIS database which allows PSB to monitor the dispensing of Schedule 8 drugs in real time. I congratulate PSB for this innovation, which is the first of its type in the country, and which I understand is being adopted by other jurisdictions.

As a result of my investigation, I reached the following specific conclusions:

- In 49 of the complaints received by my Office, the decisions made by PSB had been reasonable.

- In one complaint, the decision had not been reasonable.[3] The Department should establish a system of review which affords natural justice to a patient affected by a decision of PSB, and which provides for a thorough and objective inquiry to be made into complaints by both patients and doctors.
- While there are no other serious shortcomings in the way that PSB is operating, there are a number of areas which could be improved (these have been highlighted in the body of this report).

I make 13 recommendations to PSB and DHHS, principal among which are that:

- the Department make immediate provision for the internal review of decisions made by PSB on s 59E applications, with the right of review to be available to the practitioner concerned as well as the affected patient;
- the Department make known the existence of the internal review mechanism to the prescriber when informing him or her of the outcome of the s 59E application;
- the Department improve record-keeping in relation to decisions and authorisations;
- PSB change some of its practices to ensure compliance with s 59E;
- the Department seek changes to the Act to provide measures for enforcing compliance with s 59E and affording greater flexibility in decision-making; and
- the Department improve the reliability of the database and undertake education and liaison activities with prescribers to ensure compliance with s 59E.

Review of Opioid Prescribing in Tasmania

At the same time as my investigation, two reviews into Schedule 8 drugs were also proceeding, one at State level and one at Commonwealth level. My Office was consulted during the course of both.

The State review was commissioned by DHHS and conducted by the National Drug and Alcohol Research Centre. NDARC released its findings in late July 2012 in a report entitled *A Review of Opioid Prescribing in Tasmania: A Blueprint for the Future*.

The reviewers noted the changing landscape in relation to Schedule 8 drug availability and regulation and prescribing practices for chronic non-malignant pain, and raised a number of the same concerns that I do in this report. The reviewers also made a number of recommendations, some of which I agree with, and some of which I am unable to comment on.

The review was of much broader compass than my investigation, but it traversed some of the same ground and noted some of the same issues. In particular, the

[3] It is noted, however, that this decision was subsequently revisited and revised by PSB, when it was made aware that the complaint had been made.

review noted a lack of transparency in some of PSB's decision making, a lack of procedural fairness in some of PSB's dealings with patients, and the absence of any review mechanism for patients unhappy with a decision that has been made that adversely affects them.

There are several recommendations that are directly relevant to my investigation, and which I endorse. In particular, I agree with the following recommendations for the reasons referred to in the body of this report:

- That PSB ensure procedural fairness by stating a clearly defined role for each decision making tier, with a defined work flow and defined criteria for decision making, review of decision making and feedback to applicants (recommendation 2.2.3).
- That PSB support best practice procedural fairness through the appropriate communication to opioid prescribers of its decision making processes and decisions (recommendation 2.2.4).
- That PSB regularly engage with the Tasmanian Ombudsman to ensure ongoing procedural fairness in a conflict prone environment (recommendation 2.2.5).

While I endorse these recommendations, in my view not only should there be feedback to applicants – the practitioners seeking authorisation - and procedural fairness afforded to prescribers, there should also be an avenue of review (and procedural fairness) for the people most affected by the decisions of PSB - the patients themselves.

A draft of this report was provided to the Chief Pharmacist and the Chief Medical Officer and their comments and response to the recommendations sought. Comments and responses were given, and, where appropriate, these have been included in the body of the report.

INTRODUCTION

1. Background

1.1 In 2007, my Office received the first of over 50 complaints about decisions made by the Pharmaceutical Services Branch of the Department of Health and Human Services, in relation to the authorised prescribing of opioid analgesics. These decisions were initially made under ss 20 and 22 of the *Alcohol and Drug Dependency Act 1968*; after 2009, however, they were made under s 59E of the *Poisons Act 1971*. For convenience this report will, for the most part, refer to s 59E of the Poisons Act *(*even though it may be describing some situations which arose under the previous Act).

1.2 All of the complainants had been prescribed opioid pain medication or similar substances over periods of time, sometimes over very long periods (even decades), for the treatment of chronic, non-malignant pain. The complaints were similar in nature and contained allegations either that:

- the amount of drugs that could be prescribed to the complainant had changed; or
- the type of drug that could be prescribed had changed; or
- changes had been made to the frequency or location for pickup of the drugs.

1.3 The complainants alleged that they were no longer getting adequate pain relief, or were suffering increased costs for dispensing or travel, or had increased inconvenience or distress. A recurring feature of the complaints was that the complainants appeared to have little or no knowledge of why decisions had been made to alter their medication regimes, and they complained that there was no one to whom they could take their concerns in the Department because PSB would not talk to them.

1.4 As the number of complaints increased, all raising similar issues, it became apparent to my predecessor, Mr Simon Allston, that the most efficient way of addressing them would be by way of an own motion investigation. Mr Allston wrote to both the Minister for Health and the Secretary of DHHS on 23 March 2011, giving notice under s 23(2)(a) of the *Ombudsman Act 1978* that he proposed to carry out an investigation on his own motion into the administration by DHHS of s 59E of the *Poisons Act 1971*.

2. Jurisdiction

2.1 Under s 12(1) of the *Ombudsman Act 1978*, the Ombudsman may investigate any administrative action taken by, or on behalf of, a public authority. DHHS is a public authority as defined in s 4 of the Act. The administrative actions involved are decisions made by delegates of the Secretary of DHHS, in

response to requests from medical practitioners and others, to authorise the prescription of particular drugs to their patients.

2.2 Section 13 of the Act provides that an investigation authorised by the Act may be carried out on the Ombudsman's own motion.

3. The Legislation

3.1 Section 59E forms part of Part VA of the Poisons Act, and needs to be understood in the context of that Part (see Appendix A).

3.2 In brief, s 59E empowers the Secretary of DHHS, on application in respect of a person, to authorise a medical practitioner, dentist or authorised nurse practitioner to make available a narcotic substance or specified substance[4] for the use of that person.

3.3 Section 59C creates offences relating to the prescribing and dispensing of narcotic substances. Among other things, it prohibits certain conduct, namely making available a narcotic substance or a specified substance to any person:

- who the practitioner has reason to believe is a *drug dependent person* without authorisation;
- who the practitioner has reason to believe is *exhibiting drug-seeking behaviour*;
- for any period longer than *the prescribed period*; and
- who has a history of obtaining a notifiable restricted substance, a narcotic substance or a *prohibited substance* for a non-medical purpose or of unlawful possession or unlawful supply of a notifiable restricted substance, narcotic substance or prohibited substance.[5]

3.4 The section also makes it an offence for a medical practitioner, dentist or authorised nurse practitioner to make a notifiable restricted substance, a narcotic substance or a prohibited substance available to a person if the practitioner knows or ought to know that the person is the subject of an existing authority under s 59E(1), not being an authority which applies to the practitioner in question.

3.5 Section 59D of the Act creates important exceptions to the application of s 59C. In brief, it provides that nothing in s 59C prevents the making of a notifiable restricted substance, narcotic substance or specified substance available for the use of a person who is receiving:

- emergency treatment as an initial response to trauma or an acute condition; or

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[4] Definitions for all these terms can be found in s 3(1) and s 59A of the Act (see Appendix A).

[5] Definitions for all of the above terms can be found in s 3(1), s 4 and s 59A of the Act (see Appendix A).

- medical treatment as an inpatient at a hospital; or
- medical treatment in a treatment centre;[6]

where the substance is made available by or with the authority of a medical practitioner or nurse practitioner acting in the course of his or her duties at that place.

3.6 Part VA of the Poisons Act effectively replaced Part III of the Alcohol and Drug Dependency Act in 2009. The wording of the Alcohol and Drug Dependency Act, in particular some of the definitions, was different to that in the amended Poisons Act. The extent of the controls in place, however, was similar and I do not consider it necessary for the purposes of this report to outline in detail the way in which those earlier provisions operated.

3.7 The obvious purpose of Part VA – made most apparent by s 59C - is to control the prescription and therapeutic use of drugs of addiction, to minimise the potential for harm to those to whom they are given, and to minimise their misuse, including the potential for diversion.

3.8 Various regulations made under the Act are also relevant to its operation. For example, s 59C(3) requires reference to the *Poisons (Prescribed Periods) Order 2009* which sets out the period for which a drug can be prescribed without the prescribing medical practitioner seeking an authorisation under s 59E. For most narcotic substances this is 60 days (for some it is less and for some it is nil). Any doctor who has reason to believe that a patient is drug dependent, however, must seek an authorisation immediately.

3.9 The 60 day period only operates where a patient has shown no signs of drug-seeking behaviour or of drug dependence. If information points to the patient having a history with drugs, then the doctor must seek authorisation immediately. Drug-seeking behaviour is defined in s 4 of the Act,[7] and indicators might include the patient:

- seeing multiple doctors for treatment of the same condition;
- having a history of obtaining drugs on the street;
- having visible track marks from injecting;
- alleging lost or stolen prescriptions;
- coming in early to collect their prescription; and/or
- trying to escalate the amount of drugs prescribed.[8]

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[6] Defined in s 3(1) see Appendix A.

[7] See Appendix A.

[8] If there are any signs of drug seeking behaviour in a patient seeking a notifiable restricted substance or narcotic substance, then there is a mandatory requirement under s 59B that the practitioner notify PSB.

4. The PSB Database

4.1 A major administrative innovation at PSB in recent times has been the development of a new, real-time reporting database, DAPIS (Drugs and Poisons Information System). In nearly every case, the moment a patient has a prescription dispensed the transaction will immediately come up on PSB's database and be visible to PSB pharmacists. Approximately 95 per cent of all pharmacies in Tasmania now provide dispensing details for narcotics to PSB on-line through DAPIS at the time they are dispensed. This enables the almost-instantaneous monitoring of Schedule 8 drugs when they are dispensed in nearly all Tasmanian pharmacies.

4.2 Only one doctor (or another doctor from the same practice) is allowed to prescribe opioids for a patient at any one time. A GP must check that no other doctor is currently prescribing opioids to that patient[9] and, where the patient changes doctors, an application for authorisation has to be submitted by the new GP.

4.3 At the time this investigation commenced, PSB was also working on a second online database called DORA (Drugs Online Remote Access), a simplified version of DAPIS for the use of doctors. The introduction of this is likely to be delayed due to the fact that the DORA/DAPIS software has now been licensed to the Commonwealth, which will eventually lead to the rollout Australia-wide of the Electronic Recording and Reporting of Controlled Drugs database. Depending on Commonwealth enhancements to the system, it may be some time before DORA is available.

5. Delegated Decisions

5.1 When an application for authorisation is received by PSB, a decision has to be made by a delegate of the Secretary to grant the application and authorise the drug requested, or to refuse it.

5.2 The delegate can authorise the prescription of a particular drug as requested by the GP, or refuse to authorise the drug requested, or authorise it with different conditions. Authorisation may include one or more of the following conditions:

- the prescription is to be lodged with one nominated pharmacy;
- the drugs are to be dispensed weekly, twice-weekly, thrice weekly, daily, or daily under supervision from the pharmacy;
- the patient is to see a specialist within a specified time;
- a drug different to that requested is to be dispensed;

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[9] Regulation 10 of the Poisons Regulations 2008.

- a lesser quantity of the requested drug is to be dispensed; and/or
- the drug is only authorised for a short time.

6. The Drugs

6.1 Authorisations mainly concern the kind of drugs commonly referred to as Schedule 8 drugs. Schedule 8 lists, among other drugs, opioids such as oxycodone and morphine, which are used for strong pain relief. These drugs are controlled because long-term use of opioids leads to a physical dependence, and because they are also potentially dangerous.

6.2 As well as the drugs contained in Schedule 8, s 59E also applies to *specified substances*: substances which have been declared by the Minister to be a specified substance for the purposes of Part VA. Specified substances are listed in Schedule 4, but to date, only alprazolam in combination with an opioid has been declared.[10]

6.3 There has been a significant increase in the last 15 years in the incidence of the prescription of Schedule 8 drugs for chronic non-malignant pain. Despite the fact that most of these prescriptions have been for adults over the age of 50, with the steepest increase in rates of prescribing being to patients aged over 70 years,[11] this increase has been a cause of concern. This concern has arisen because the drugs involved can be dangerous when not prescribed by a medical practitioner with the requisite skill and experience.

6.4 As well as the dangers occasioned by poor prescribing practices, there are also dangers when the patient does not use the drug as directed, and opioids feature heavily in coroners' reports concerning accidental drug-related deaths. As well as the safety factor, all of these drugs, to a greater or lesser extent, have a street value on the black market. Each year, people who have been legitimately prescribed opioids are prosecuted in the Magistrates Court for selling on some or all of their drugs.

7. The Complaints to My Office

7.1 All of the early complainants had been prescribed opioids in accord with the legislation for long periods of time, sometimes decades. Some had a long history with the same doctor or pain specialist, whereas others moved from one doctor to another with regularity. Some of the doctors involved made

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[10] It would appear that there are moves afoot at the Commonwealth level to transfer alprazolam to Schedule 8. It was described to this Office as "seductive" to drug-seeking patients and the RACGP and RANZCP recommend that, ideally, it should only be taken for short periods of time.

[11] See Hall & Farrell 2011 "Minimising the Misuse of Oxycodone and Other Pharmaceutical Opioids in Australia" *MJA* 195 (5)

the initial decision to prescribe their patients opioids and some of them inherited a prescription regime when they acquired a new patient.

7.2 It is possible, and in some cases likely, that over time obtaining opioid drugs had become a major focus of some complainants to my Office. In addition, some of these complainants may have been challenging for their doctors. It is nevertheless important to note that all of these complainants had major health problems and that, at some point, a doctor had decided to start treating the pain associated with these health problems with opioid drugs. While treatment with opioids is not always clinically necessary (as PSB rightly asserts), the fact remains that some doctors in the past have formed the view that it was necessary for some of their patients.

7.3 The complaints, in most cases, related to changes to the conditions imposed on the prescribing of the drugs by PSB. Complainants often asserted to my Office that there had been no prior consultation with them or with their GP before these changes were instituted.

7.4 One of the reasons also asserted for complaints to my Office was that neither the doctor nor the patient understood why new or different conditions had been imposed on the prescription and dispensing of opioids. As best practice in relation to the use of opioids is subject to constant change and reassessment, doctors and patients may be at a loss to understand the reasons behind changes in prescriptions without adequate explanation from PSB.

7.5 The complaints to my Office, taken together, raised the following concerns:

- pickup regimes had been cancelled and patients had been required to attend a treatment centre in order to have daily dosing (those to whom this applied, it subsequently transpired, had been suspected of using their drugs inappropriately);
- some patients attending treatment centres were required to change from physeptone to buprenorphine (both are synthetic opioids but with different properties);
- buprenorphine, it was claimed by some, did not treat their pain as effectively as physeptone;
- patients not required to attend a treatment centre had to pick up their prescription on a much more frequent basis than that to which they had become accustomed, such as daily, every second day, or every week rather than fortnightly or monthly;
- because of restrictive pick-ups, patients were not able to go away even for short periods and, if they were working, it restricted the kind of work they could do;

- the drugs they had been prescribed were changed or the dosage had been reduced, and they claimed they were no longer getting adequate pain relief;
- dispensing costs at the pharmacy increased ;
- travelling costs to and from the pharmacy or treatment centre had also increased;
- patients living in rural areas who had to travel long distances to obtain medication complained that the additional cost meant that they could no longer support themselves on the disability support pension;
- complainants felt humiliated because they felt they were being treated like *addicts* (their words); and
- there was no one in the Department to whom they could complain about their treatment, and PSB staff would not speak to them.

7.6 PSB responded to these concerns as follows:

- PSB is responsible for the administration of the Poisons Act in the interests of public and patient safety.
- In some cases, the prescribing practices of the doctors involved were manifestly unsafe.
- The need for opioids was not always clinically necessary.
- Where there was a specialist supporting the patient's current regime, PSB would not interfere.
- The rising death rate in Tasmania from such drugs as oxycodone has led to inquests which have commented upon the apparent ready availability of such drugs, and Coroners have, at times, been critical of the monitoring of these drugs.[12]
- Dispensing costs should not change with pickup conditions, as costs are set under the Pharmaceutical Benefits Scheme. The PBS now makes an allowance for rationed supply as it is recognised by the Commonwealth that there are patient safety issues which require rationed supply. In these situations there is just one dispensing but the supply is rationed over a number of visits. The allowance is paid as a total allowance to pharmacies participating in the rationed supply. If pharmacies charge extra to give out medication daily (for example), this is not a dispensing cost but a form of service fee that they have imposed themselves as a commercial decision: it does not occur in all pharmacies or in all circumstances.
- It is standard practice for PSB to ring GPs when it is refusing to authorise drugs or is imposing conditions and in some cases GPs don't pass on this information to the patient.

[12] For example 2007 TASCD 061 (deceased unnamed).

- PSB will not talk to people on the phone where its officers cannot verify the identity of the caller. New complaint forms have been developed for written requests for review in the future.

7.7 It is obviously a difficult area where, over the last 10 years, different styles and philosophies of practice in the treatment of non-malignant chronic pain have tended to conflict. PSB referred to the NDARC review which identified that doctors have not been well enough prepared in their graduate and postgraduate education in pain and addiction medicine needs. In NDARC's view, this has led to the varying clinical practice and an acknowledgement that issues with opioids are often the result of doctors not getting opioid prescribing right.

7.8 I would hope that the question of what constitutes good prescribing practice will be resolved in the process of implementing the Opioid Review.

8. Pharmacists

8.1 Referred to in the Act as *pharmaceutical chemists*, pharmacists do not have a specified role under s 59E, even though they provide so much of the information on which PSB relies. They are, however, subject to the stringent requirements with regard to dispensing opioids contained in the Poisons Regulations, and to a professional standard for the safe dispensing of such drugs. Any non-compliance with the standard can be referred to the regulatory body, the Australian Health Practitioners Regulation Agency, and can result in a number of consequences, including de-registration.

8.2 For this reason, pharmacists often take an active role with regard to the supply of opioids and will contact PSB when they are concerned or uncertain about a particular prescription that has been presented.

THE INVESTIGATION

9. Methodology

9.1 Prior to the investigation commencing, a good deal of background research was carried out by my Office into the issues raised by the complaints we had received. The review of literature supporting the development of Australia's *National Pharmaceutical Drug Misuse Strategy* published by the National Centre for Education and Training on Addiction in 2011 was very useful. A list of all background reading used in researching this investigation can be found in the Bibliography.

9.2 The following documents were also obtained and reviewed:

- Relevant legislation:
  - Poisons Act 1971;
  - Poisons Regulations 2008;
  - Poisons (Declared Restricted Substances) Order 1990;
  - Poisons (Prescribed Periods) Order 2009;
  - Poisons (Drugs of Dependence) Order 2009;
  - Poisons (Specified Substances) Order 2009;
  - Poisons List Order 2001[13];
  - Alcohol and Drug Dependency Act 1968;
  - Alcohol and Drug Dependency Regulations 1999;
  - Misuse of Drugs Act 2001; and
  - Poisons Standard 2011;
- Documents provided by PSB and ADS as a result of various meetings with staff of my Office which took place in 2011, including prescribing policies, working documents, copies of forms, guidelines, etc.

- Documents provided by PSB during the course of the investigation including sample forms for the recording of complex decisions (after advice from the EAP) and for processing section 59E applications (Appendix C).

- Information provided during the course of the two reviews into pharmaceuticals that were conducted during 2011 - 12, one on pharmaceutical drug misuse commissioned by the Inter-Governmental Committee on Drugs and the other on opioid prescribing commissioned by DHHS. The final reports on these two reviews by NDARC and NCETA were also accessed (see bibliography).

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[13] This Order contained Schedule 8 until July 2012 when the Adoption of Uniform Standards took effect.

- Other State government reviews into prescribing policies and drug strategies in Tasmania including:
    - the *Tasmanian Drug Strategy* (TDS) 2005 – 2009;
    - Future Service Directions for Alcohol, Tobacco and Other Drug Services for the period 2008/09 – 2012/13;
    - the Tasmanian Report of Benzodiazepine and Pharmaceutical Opioid Misuse and Their Relationship to Crime (funded by the National Drug Law Enforcement Research Fund);
    - the 2008 Review of Alcohol, Tobacco and Other Drug Services in Tasmania and its preceding discussion paper of 2007; and
    - 2010 *Report of Actions and Achievements* regarding the Tasmanian Drug Strategy, and the draft report of the Tasmanian Opioid Pharmacotherapy Policy and Clinical Practice Standards.

9.3 My investigator also spent a significant amount of time at PSB, during which she was able to access and navigate its database and to observe the decision-making practices of the pharmacist/delegates.

AREAS OF CONCERN

10. Communication/Review

10.1 There is no avenue of redress or review available to patients and doctors affected by PSB's decisions. In fact, PSB has a policy of not engaging at all with the patients for whom applications are made by medical practitioners. It justifies this by saying that its relationship is with the doctor who is making the application under s 59E(1), not the patient.

10.2 In my view, it is not reasonable to refuse to engage with patients, the very people about whom, and in relation to whose medical treatment, decisions are being made, even though the formal request for these decisions comes through a third party (their prescribing doctors). Procedural fairness demands that patients are afforded the opportunity to understand and make submissions on decisions of this nature.

10.3 With no communication, there is no possibility of review under the current system being used by PSB. In my view, it is essential that DHHS put a review procedure in place. There will be some situations in which a decision should not be allowed to stand unchallenged.

10.4 When a patient or doctor seeks a review it should be carried out either by someone in PSB who has not been previously involved in the case, or by an independent officer in the Department under a separate review procedure. The complainant should be afforded natural justice in relation to a decision which affects him or her, and a reasonable, thorough and objective enquiry should be made into the complaint.

10.5 My Office will then accept complaints where the patient is unhappy with the Department's response. This is my Office's intended role; reviewing matters where a statutory authority has already made a considered response as part of its own review process.[14]

Recommendation One

That DHHS make immediate provision for the internal review of decisions made by PSB on s 59E applications, with the right of review to be available to the practitioner concerned and the affected patient. This right of review should be made known when informing the practitioner of the decision on their s59E application.

[14] It is of note that the NDARC' report also recommends that PSB ensures procedural fairness and that there be a system providing for the review of decisions.

Recommendation Two

That PSB cease its practice of failing to engage with patients who are affected by its decisions.

Response to Recommendation One and Two by PSB

PSB advised that a new process for review is being established to enhance current processes. PSB will develop a patient complaint form so that a response can be provided to written complaints. PSB also noted that it has responded to written communications from patients, and does not ignore correspondence, but it does not take *cold calls* from patients in the interests of privacy and safety. It is intended that the new process and its associated forms will result in a greater level of transparency and accessibility.

11. Delegation and Advice

11.1 Decisions on whether to authorise the availability of a Schedule 8 drug are made, according to the Act, by the Secretary of the Department. Obviously, where thousands of applications are approved annually, decisions whether to authorise or not have to be delegated.[15] The people authorised to make these decisions are the pharmacists at PSB.

11.2 Although only the Secretary/delegate can make a decision under s 59E, the decision-making process within PSB appears to have reached a point where delegates consult with each other and with a number of medical practitioners and specialists, either the CMO or the EAP, and a form of "collective decision-making" has evolved. This is strenuously denied by PSB, though it concedes that the often robust clinical discussions involving EAP members could lead an observer to draw that conclusion. Whether fact or perception, however, the respective roles of the CMO, EAP and delegates must be, and remain, clearly defined and separate.

11.3 I have no doubt that the input from highly trained specialists is of enormous benefit to PSB. It is my view, however, that it must be clear – to an observer as much as the participants - that these specialists are a valuable source of advice only, and that the substantive decision on an application for authorisation remains solely with the responsible delegate.

[15] PSB has advised my investigator that more than 7,500 authorisations were processed in the 2012 calendar year.

11.4 It is my view that s 59E requires the decision to be made by the Secretary (singular) and by delegation that passes to a delegate (singular). Therefore a delegate, when delegated to make a decision, can only make that decision him or herself. While it may be appropriate to consult within the agency with other delegates, or outside the agency to take advice from suitably qualified people, nevertheless the decision must be made by one delegate and one alone.

Recommendation Three

That PSB alter its practices so that where a decision on an application under s 59E is made after consultation with a Consultant Medical Officer or the Expert Advisory Panel, it is made clear to all – including the prescriber - that the decision is made by the delegate alone, and the role of the CMO or EAP is only an advisory one.

Response to Recommendation Three by PSB

While maintaining that there has been no collective decision making, letters produced by PSB now better inform prescribers that the decision is that of the delegate and that advice may or may not have been taken from the EAP or CMO. Further as part of the Opioid review, a GP/patient form is being developed (and will be workshopped through the GP organisations) that will ensure:

- GPs inform patients of the benefits and risks in starting opioid treatment; and
- patients have given informed consent to the treatment and the required regulatory obligations.

12. Record Keeping

12.1 All decisions made by an agency should be capable of being audited and this can only be done where adequate reasons have been recorded. My investigator's review of files found that, in some cases, complex decisions had been recorded in the most rudimentary way, which makes them hard, if not impossible, to audit.

12.2 The standard of recordkeeping of delegates in relation to decisions, particularly those decisions which have been made in complex cases, often after having received advice from the EAP or CMO, causes me concern. In my view, clear and adequate reasons should be recorded for each and every decision, particularly for those that are complex and potentially contentious.

Recommendation Four

That recordkeeping should be improved so that all decisions in relation to s 59E are adequately recorded. The record should also clearly indicate which delegate has made the decision.

Response to Recommendation Four by PSB

New decision recording sheets have now been developed which will form part of a patient's records and will be available for any clinical review.

13. PSB's Relationship with Doctors and Specialists

13.1 The relationship between PSB and the majority of doctors with whom it deals appears to be a cooperative one and this is to be commended; it would be impossible for PSB to administer s 59E without the cooperation of medical practitioners.

13.2 Schedule 8 drugs are potent and dangerous and there is a particular need for high levels of skill and training in their prescription. Although there are many skilled and dedicated doctors prescribing opioids, on occasions the competence of the prescribing practitioner might be open to question.

13.3 In some medical practices, only the older and more experienced doctors deal with opioid-seeking patients. On the other hand, as these patients tend to be more difficult, demanding and aggressive than others, there are some practices that allocate them to their newest doctors, which is an unsatisfactory situation.

13.4 Clearly there needs to be support, particularly for younger doctors and those coming from overseas, and PSB appears to be providing this within the limited resources available to it. I understand that PSB has been able to devote some funds, on a *one off* basis, to the implementation of the Tasmanian Review of Opioid Prescribing (released on 25 July 2012). This will only provide limited assistance with improving skill levels among medical practitioners, however, as it is not a recurring budget item.

13.5 I am confident that the Tasmanian Review of Opioid Prescribing will lead to a working policy for the prescription of opioids which will ensure that there is a uniform and consistent approach to prescribing across the State.[16]

14. Specialist Reports

14.1 The current policy of PSB requires that, in most situations, opioids can only be prescribed for a limited time before a report from a pain specialist, an addiction specialist or some other specialist is required. The problem with these reports, however, is that they often provide no information in the area of most concern to PSB; that is, recommendations about ongoing pain relief.

14.2 In my view, PSB needs to be much more directive in relation to the information required from a specialist. If information on pain medication is

[16] The NDARC report also has a strong focus on practitioner education.

essential, then PSB should formulate a template to be sent to specialists requiring the specialist to comment on the specific opioid drugs for which authorisation is sought, with the rider that unless the specialist endorses the continuing or proposed medication regime, it will not be authorised. One of the results of better and more specific specialist reports might be that there would be less need for CMO and EAP meetings.

Recommendation Five

That PSB adopt a more directive approach in requiring information from specialists specifically in relation to Schedule 8 drugs.

Response to Recommendation Five by PSB

PSB agrees with the recommendation and suggests that education and information should be provided to specialists.

14.3 In my view there would be significant benefit in enhancing specialist pain services in Tasmania and in creating (and funding) increased opportunities for medical undergraduates to be educated in the areas of addiction and pain medicine.

15. Enforcing Compliance with the Act by Prescribers

15.1 The Poisons Act and the Poisons Regulations contain a number of offences in relation to the supply of narcotic substances. Sections 59B and 59C make it an offence to make available narcotics to drug dependent persons without the authority of the Secretary, or where the medical practitioner *knows or ought to know* the person is subject to an authority under s 59E. These offences carry fines of up to 50 penalty units.[17] A more broad ranging offence is created by Regulation 11, which provides that a person must not supply a narcotic substance to a person who is not authorised by the Act or the Regulations to have possession of that narcotic substance. An offence under the Regulation carries a penalty of up to 10 penalty units.

15.2 I am not aware of any prosecutions having been instigated for offences under the Act. In fact, a notice sent out to doctors by the Department entitled *Important Information for Prescribers* does not even mention the presence of offences in the Poisons Act.

15.3 It seems that it is PSB's policy, as noted previously, to work cooperatively with doctors as far as possible, relying on knowledge among GPS of the

[17] In other words, a fine of up to $6 500 - one penalty unit is currently $130.

potential of referral to AHPRA over professional practice issues to obtain compliance, rather than on the threat of prosecution. PSB advised me that professional practice issues across any professions which have a role under the Poisons Act can result in a report to AHPRA, and PSB does use its powers under section 92 of the Act to remove the right of professionals to prescribe, sell or supply Schedule 8 drugs. This has occurred on a number of occasions. PSB states it seeks to ensure the right balance between policy, regulation of practice and enforcement. Prosecution is generally the last resort.

15.4 In the interests of efficiency, a compliance strategy is needed in relation to minor breaches in order to ensure not only the ongoing effectiveness of the new database but, more importantly, the integrity of the administration of the Act. In my view, it would take only a very few successful compliance actions to change how doctors approach their responsibilities under the Poisons Act.

15.5 It is possible that when DORA becomes available online, some of these problems may be resolved, and I understand that some form of infringement penalty is being looked at by the Department. I recommend that this be proceeded with.

Recommendation Six

That PSB expand the current options to enforce compliance by medical practitioners with s 59E to include lesser infringement offences, and that PSB enforce compliance with s 59E more rigorously than in the past. This would include consideration being given to amending the Act to make a failure to impose the conditions contained in an authorisation an infringement offence.

Response to Recommendation Six by PSB

PSB advises that amendments to allow for infringement notices were to be included in recent amendments to the Poisons Act. The need for consultation and other legislation, however, resulted in their being postponed until a new Act is written in two years or so.

16. Changes to Authorisations

16.1 Another aspect of s 59E about which I have concerns is the inability of delegates to change the conditions on authorisations during their currency. Section 59E makes provision for a medical practitioner to apply for authorisation, and for the Secretary or the delegate to authorise the drugs requested, either with or without conditions. There is no provision in the

Act, however, for conditions to be imposed or changed by the delegate once an authority has been granted.

16.2 It is clear that there are situations where a need arises urgently to change the conditions for the prescription of certain drugs. Situations may well also arise where it would be unsafe for an authorisation to continue to run on the conditions initially imposed. The Act or Regulations should ideally be amended to allow changes to conditions to be made as, for example, Regulation 19(3) allows changes in relation to certain narcotic substances.[18]

16.3 There is also a need for certainty in cases where the change to the authorisation is instigated by the medical practitioner. The wording of the Act needs to be clarified so that a current authorisation extinguishes the previous authorisation where the previous authorisation still has time to run.

Recommendation Seven

That the Department propose amendments to s 59E to allow conditions to be changed as the situation requires, without further application by the practitioner, and to make it clear that the grant of a fresh authority extinguishes all previous authorities.

Response to Recommendation Seven by PSB

PSB has indicated that it will need to seek the Solicitor General's advice in this regard. Previous advice had indicated that, under administrative law, decisions could be revisited at any time. Clarity is required to determine whether that advice applies in these specific circumstances.

17. Keeping Pharmacists Informed

17.1 Section 59E makes no reference to pharmacists. Pharmacists are more widely the subject of the Regulations and professional standards, and their role under the legislation with regard to narcotics appears to be mainly one of record-keeping. It seems, however, that PSB expects pharmacists to play a much wider role than this in monitoring Schedule 8 drugs, and a failure to comply with this expectation may result in a notification to AHPRA. In order to monitor successfully, pharmacists need to be aware of the particulars of individual authorisations.

17.2 Pharmacists do not always have access to the information that a medical practitioner does, including the conditions imposed on an authorisation. It

[18] "The Secretary may at any time in writing revoke or amend a general authorisation issued under this regulation".

would therefore seem logical that where a condition requires there to be one nominated pharmacy, then that pharmacy should be provided with a copy of the authorisation conditions.

Recommendation Eight

That where the conditions of authorisation require one nominated pharmacy, that pharmacy is provided with the conditions imposed.

Response to Recommendation Eight by PSB

While PSB agrees with the recommendation in principle, it believes that the manner in which the pharmacy is notified will need to be the subject of further consideration. PSB also states that patients have a choice of pharmacy and that neither PSB nor medical practitioners can direct which pharmacy must be used.

18. Written Forms

18.1 Section 59E(2) requires that an application must be in writing in a form approved by the Secretary. Only the Chief Pharmacist and the Deputy Chief Pharmacist hold a delegation in relation to forms.

18.2 In my view, s 59E(2) does not allow delegates to approve the form of application in any way they see fit. Administrative consistency requires one form should be approved and that all applications should be lodged in that form.

18.3 I understand that PSB is currently updating its forms. I also understand that DORA, when it is fully introduced, will have the facility to make online applications possible and that this may resolve the matter.[19]

Recommendation Nine

That PSB ensures that applications under s 59E(2) comply with the Act.

Response to Recommendation Nine by PSB

PSB advises that verbal applications have been taken to ensure efficiency and risk avoidance. It suggests, however, that advice is required from the Solicitor General so that it can manage verbal applications in a manner which meets the requirements of the Act, and best practice, in the interests of patient

[19] I am advised by PSB that the rollout of DORA has now commenced. It has been introduced to 40 practices thus far, though it is still in pilot form and enhancements such as on-line applications are not yet available.

safety. If the definition of emergency is narrow then this could cause difficulties.

In my view, the provisions of the Act are clear: it requires applications to be in writing except in emergencies. There is presently no basis upon which PSB can take verbal applications in non-emergency situations. It is my view that either proper and full consideration be given to whether the Act should be amended, or PSB should comply with its provisions as they stand.

OTHER AGENCIES HAVING INVOLVEMENT WITH SECTION 59E

19. Alcohol and Drug Service

19.1 By virtue of s 59D(b), ADS is not required to comply with s 59E in relation to patients in its in-patient treatment centres, and can make Schedule 8 drugs available to them as it sees fit. With the exception of inpatient treatment under s 59D(b), for all other purposes ADS must comply with s 59E or the doctor involved commits an offence under ss 59B or 59C.

19.2 ADS also runs an outpatient pharmacotherapy program as part of its addiction treatment service. This is run not only through ADS at various approved locations but also through a panel of community doctors who are trained in, and subscribe to the *Tasmanian Opioids Pharmacotherapy Policy and Clinical Practice Standards* (TOPP), which replaced the Tasmanian Methadone Policy 2000 in August 2012.

19.3 Despite the fact that all of the prescribers (including those in ADS) are required to comply with the pharmacotherapy policy, the decision in relation to conditions has to be made by a delegate of the Secretary. At the moment all delegations reside with PSB.

Recommendation Ten

That DHHS takes steps to make sure that ADS runs its pharmacotherapy program in accordance with s 59E, and that consideration also be given to the appropriateness of continuing to administer that program under the current legislation.

Response to Recommendation Ten by PSB

PSB is of the view that this is an area that ADS needs to take carriage of, with advice as to how TOPP can interface with section 59E. One of the issues is that TOPP drugs are still S8 drugs. PSB considers this another issue to be discussed with the Solicitor-General, and that it may perhaps be appropriate to exempt TOPP medication from some of the requirements of S59E.

20. Hospitals

20.1 When treating inpatients, s 59D(b) absolves hospitals from all of the offences contained in s 59C of the Poisons Act. The result of this exemption is that medical practitioners or authorised nurse practitioners treating an inpatient in hospital may provide opioids in any way they determine is appropriate.

20.2 The provisions of s 59D(b) only apply while a patient is an inpatient, however, and once he or she leaves hospital, any medical personnel who provide any prescription for any opioid which will be taken outside the hospital, must comply with the provisions of Part VA of the Poisons Act and the offences in s 59C apply in the normal way.

20.3 Where a person who has previously been prescribed opioids for the treatment of pain attends a hospital wanting the same treatment again, the doctor prescribing must turn his or her mind to s 59B and the question of whether that person is exhibiting drug seeking or drug abusing behaviour, and notify the Secretary if he or she is. It seems, however, that this does not always happen in the hospital context.

20.4 A contributing factor in this regard, is the significant problems in hospitals occasioned by the national coding for particular medical conditions.[20] For example, vascular surgeons dealing with ischaemic limb problems caused by injecting opioids might code the condition in a way which does not indicate that the person has been injecting. As a result, PSB will often be the last to know that a particular patient has this condition. There have also been situations where particular units in hospitals have not communicated with each other. It seems, however, that the presence of two Royal Hobart Hospital pain specialists on the EAP has resulted in improved communication and understanding between RHH and PSB.

20.5 Another concern arises where people are being treated in hospital and are provided with opioids by the hospital as an inpatient while they are at the same time in possession of opioids prescribed by their GP, or are entitled to obtain them. The practice appears to be that, if a patient goes into the hospital with opioids in an unopened pack, then they can be treated with that medication. If, however, the pack has been opened or the medication is in a Webster pack, then it will either be taken and held for them, or it will be replaced when they leave the hospital.

20.6 Because patients may have repeats of prescriptions for opioids which they can access when they leave hospital, some will leave hospital with more opioids in their possession than they need for the treatment of their condition and which they are authorised to have. The risk this would pose to particular problem patients is obvious.

20.7 Once the patient ceases to be an inpatient, doctors are prohibited by s 59C from making available certain drugs when they know or ought to know that the patient is already subject to an authority under s 59E. In my view, this wording puts the onus on the doctor to take reasonable steps to find out

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[20] This is one issue that the Review of Opioid Prescribing in Tasmanian looked at and recommended that acute care coding of drug misuse-related admissions be standardised and uniformly applied.

whether or not there is an extant authority in relation to the particular patient.

20.8 The 2008 *Review of Alcohol, Tobacco and Other Drug Services in Tasmania* recommended a state wide pain management service (which has still not yet been implemented and which is discussed below at 26.6). Such a service might ameliorate this situation. In the interim, an education program is needed throughout the state to alert all hospitals to the need to comply with the Act.

Recommendation Eleven

That DHHS implement an education program aimed at both state and private hospitals to ensure that all relevant hospital employees are aware of their obligations under the Poisons Act.

Response to Recommendation Eleven by PSB

PSB advises that the decision to check resides with the health professionals unless the hospital has developed some protocols to address this. It considers that this issue should perhaps be the subject of a separate recommendation directed to the hospitals concerned.

21. Police

21.1 There is frequent day-to-day contact between PSB and Tasmania Police. This contact usually takes the form of Tasmania Police ringing PSB and asking if a particular named person is authorised to be in possession of a nominated opioid drug. All of these contacts are recorded. PSB assured my investigator that no more information is provided to police than the type and number of drugs that a particular person should have in their possession. PSB advised that it would not provide personal information about a person, such as their place of residence and medical condition.

21.2 Tasmania Police, as a law enforcement agency within the meaning ascribed to that phrase in the *Personal Information Protection Act 2004*, can access personal information held by PSB where, among other things, it is reasonably necessary to do so for the purposes of *the prevention, detection, investigation, prosecution or punishment of criminal offences or breaches of a law imposing a penalty or sanction.*[21]

[21] *Personal Information Protection Act 2004*, Schedule 1, Clause 2(1)(g)(i)

21.3 Tasmania Police is of the view that, if it is investigating whether or not a criminal offence has been committed, the power in the Act to access personal information is wide enough to allow it to not only access information as to the type and number of drugs in a person's possession, but also other information (including a person's place of residence). I do not disagree with this view.

21.4 While Tasmania Police accesses information held by PSB, it does not share investigative information with PSB and does not seek to cleanse or analyse PSB data.

21.5 I recognise the need for PSB and Tasmania Police to work together to combat the passing or selling on of opioid medications. While I have no reason to question the propriety of what has occurred to date (and notwithstanding the legislative framework referred to), I recommend that PSB and Tasmania Police formalise a protocol for the exchange of information between them.

Recommendation Twelve

That PSB and Tasmania Police implement a protocol to address information sharing and data cleansing.

Response to Recommendation Twelve by PSB

A memorandum of understanding has been reached with Police but PSB advises that the process is a difficult one. Information is now only placed on the system if Tasmania Police confirm with an e-mail. Information is only given to police if they can confirm it is part of an investigation. PSB believes it reasonable to take a policy decision to ignore records more than ten years old (unless the record is very significant) in cases where there had not been further instances of problems.

22. The Director of Public Prosecutions

22.1 As far as I am aware, there have been no prosecutions under s 59C or any similar provisions in the Poisons Regulations. My investigator was informed by PSB that the Office of the DPP would refuse to take on such a case. The DPP's office, however, advised my investigator that it would prosecute if the offence was deliberate but possibly not if it was inadvertent.

22.2 I have noted above that PSB seems to prefer to proceed cooperatively with the medical profession, using as its major inducement to compliance a notification to the national registration body via AHPRA.

POLICY

23. PSB Policy

23.1 DHHS administers and oversees the distribution of most of the legitimate opioid drugs in the State:

- Through PSB it administers the manufacture, supply, prescription and distribution of all Schedule 8 medications, including the authorisation of private practitioners to prescribe opioid medication for their patients.
- Through ADS it administers treatment centres where those with addiction problems can be treated as inpatients.

It also has an advisory role with the new Tasmanian Health Organisations (the public hospitals) where decisions are separately made by employees in relation to the treatment of inpatients with opioid drugs. The level of control it has brings with it the need to formulate and implement policy around the administration and use of opioid drugs.

23.2 Decisions must be open for review and a clear, structured and reasonable set of guidelines and policies assists with this task. In my view, PSB should, as far as practicable, record and codify all of its current practices and policies to ensure consistency of use and ease of audit of decisions. In addition, PSB should ensure that this information is available to GPs.

Recommendation Thirteen

That PSB should, as far as is practicable, record and codify all of its current practices and policies to ensure consistency of use and ease of audit of decisions. In addition, PSB should ensure that this information is available to GPs.

Response to Recommendation Thirteen by PSB

PSB advises that steps have already been taken to ensure compliance with this recommendation.

24. State Approach to Opioid policy

24.1 Because prescription opioids provide benefit to legitimate users but also have the potential for harm in other ways, there has been a proliferation of recent reviews and reports concerning their prescription and use.

24.2 At the time that this investigation was started, two new reviews were in progress, one national and one at state level. Both of these are now

complete. NCETA released a national review in February 2012 entitled *Pharmaceutical Drug Misuse Problems in Australia: Complex Issues, Balanced Responses*. I have already referred to the NDARC review.

24.3 Most of the recommendations and suggestions arising from the NDARC review seek to establish good clinical practice for the management of chronic non-malignant pain and aim to inform policy and practices regarding opioid analgesic prescribing. The review should contribute to improved management of chronic non-malignant pain and hopefully assist to reduce the risk of harms associated with prescription opioids. It should also lead to the implementation of new guidelines which will enhance the clarity of information available to both GPs and patients.

24.4 I must, however, record my concern about the number of previous reviews which appear to have made recommendations that have not yet been implemented. Clearly this is a time of great change in relation to the supply of opioids. The plethora of research papers and articles and reviews indicates that this is not an easy area in which to make policy. While opioids undoubtedly have short term beneficial use, there is no consensus around long-term use.[22] This may be because it is ethically difficult, if not impossible, to undertake a proper study on long-term use when the control subjects are people in pain.[23]

24.5 There are many bodies - local, national and international - which are struggling to formulate policy in this area. As a result, even at the local level, there is a danger of 'stakeholder fatigue' due to the volume of reviews being conducted.[24]

24.6 I make two comments about these reviews:

- Firstly, a recommendation for a state wide pain management service was put forward in the 2008 *Review of Alcohol, Tobacco and Other Drug Services in Tasmania,* and this does not appear to have been implemented. The recommendation seems eminently sensible with a real possibility of improving the quality use of opioids.
- Secondly, the ATOD *Future Service Directions* five-year plan recommended a client focused system. As PSB insists its only clients are medical practitioners, at the very least these doctors must be meaningfully engaged in any policy change.

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[22] This debate is set out in chapter 4 of Nicholas et al 2011 Responding to pharmaceutical drugs misuse problems in Australia – a review of the literature supporting the development of Australia's National Pharmaceutical Drug Misuse Strategy NCETA p109

[23] Nicholas et al 2011

[24] Tasmanian Drug Strategy 2005 – 2009 Report of actions and achievements August 2010 p14

24.7 I am hopeful that the recommendations from NDARC to DHHS in relation to opioid prescribing, which resulted from a wide consultation among stakeholders, will be acceptable to the majority of the medical profession. I look forward to the recommendations of the Tasmanian review being implemented and forming part of a stable policy for at least some years to come.

OTHER ISSUES

25. Definition of Drug Dependency

25.1 The definition of *drug dependent* changed in 2009 with the amendments to the Poisons Act. The amended version accords more closely with the commonly perceived definition of addiction. The previous definition was problematic and was possibly the cause of some confusion among GPs.[25]

25.2 It is now three years since the amendments were made and I am not aware of any decisions relying on the previous definition that are still operative. I am aware, however, that there may be situations where patients reappear and decisions may need to be made under s 59E as to whether they are drug dependent or not. I would advise that great care should now be taken when referencing any decision made prior to 2009 in relation to drug dependency. Not only did the definition change but, based on the files of early complainants to my office, my impression is that not all doctors understood the requirements of the previous definition.

26. Terminal and Cancer Patients

26.1 PSB's policy on terminal patients is to give the treating doctor wide discretion.

26.2 I understand that PSB receives a regular report from the Registrar of Births Deaths and Marriages and all deaths are noted in the database and are used to close the files on all of those who have had prescriptions authorised under s 59E. This means that if anyone presents a prescription or a pharmacist

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[25] S 4(1) of the ADDA defined dependence as:

a condition of a person arising from the taking of a substance that is manifested by –

(a) an interference with his bodily or mental health; or

(b) an interference with his capacity to engage in ordinary relations with other persons or to earn his own livelihood or to undertake any duties or perform any functions that he might reasonably be expected to undertake or perform.

and s 4(4) provided:

For the purposes of this Act a person shall be regarded as suffering from drug dependency if he takes drugs to the extent that –

(a) he is thereby dangerous at times to himself or others or incapable at times of managing himself or his affairs; or

(b) he shows prodromal signs of becoming so dangerous or so incapable.

For the definition of *drug dependant person* in the *Poisons Act*, see Appendix A.

dispenses drugs after the date of death of the particular patient, the system will activate an alert and PSB will investigate.

27. Legislation in Other States

27.1 Having looked at the legislation in other states equivalent to the Tasmanian Poisons Act, and the resulting practices and policies flowing from that legislation, it is clear to me that there is not a uniform approach to the control of Schedule 8 drugs, beyond a consensus that some form of control is needed. While all states have schedules of controlled drugs similar to that in Tasmania, not all states administer or control these drugs in the same way. PSB points out that Victoria and New South Wales do not currently monitor Schedule 8 drugs and authorities are only on the request of the prescriber.

27.2 The rollout of ERRCD will change the landscape significantly across Australia and there will be a governance structure put in place under a Committee created under the AHMAC structure.

27.3 As matters stand, I note that the equivalent Victorian legislation provides for the formal review of a refusal by the Secretary to issue or renew an authorisation by way of appeal to the Magistrates' Court on the application of any person who feels aggrieved by that refusal.[26]

27.4 PSB's view is that magistrates would not have the expertise to make the sorts of decisions required. Though review through the Magistrates' Court might not always be a quick process, given the amount of work that it already has to deal with, technically I see nothing wrong with it. The success of such a scheme of review would be dependent on adequate training and resourcing, but magistrates already sit as coroners and make detailed medical findings.

[26] Drugs Poisons and Controlled Substances Act, s 37(1).

CONCLUSION

28.1 Despite the number of complaints received by my office, in my view there are no serious shortcomings in the way that PSB is administering s 59E. There are a number of areas which could be improved and these have been highlighted within the report. In any agency there will be areas needing improvement and the scrutiny of an outside auditor should not be seen as a negative process, but one that brings benefits to the agency and to good administration generally.

28.2 As well as commenting on areas needing improvement, I also need to applaud things which are done well and in this respect I cannot speak too highly of the introduction of the DAPIS database by PSB, which leads Australia in its ability to monitor real-time dispensing of Schedule 8 drugs. In view of PSB's low staffing levels and ongoing commitments in other areas, this is an excellent innovation and I can only hope that PSB continues to have the resources to improve and develop it.

28.3 I have noted the difficulty of the environment in which PSB works, and its perceived need for security in dealing with difficult and sometimes threatening patients. It is nevertheless my view that the Department should institute as a matter of priority a process of review for doctors and patients affected by the decisions of PSB.

28.4 This was among the recommendations I made in the body of the report, a full list of which follows.

RECOMMENDATIONS

1. That DHHS make immediate provision for the internal review of decisions made by PSB on s 59E applications, with the right of review to be available to the practitioner concerned and the affected patient. This right of review should be made known when informing the practitioner of the decision on their s59E application.

2. That PSB cease its practice of failing to engage with patients who are affected by its decisions.

3. That PSB alter its practices so that where a decision on an application under s 59E is made after consultation with a Consultant Medical Officer or the Expert Advisory Panel, it is made clear to all – including the prescriber - that the decision is made by the delegate alone, and the role of the CMO or EAP is only an advisory one.

4. That recordkeeping should be improved so that all decisions in relation to s 59E are adequately recorded. The record should also clearly indicate which delegate has made the decision.

5. That PSB adopt a more directive approach in requiring information from specialists specifically in relation to Schedule 8 drugs.

6. That PSB expand the current options to enforce compliance by medical practitioners with s 59E to include lesser infringement offences, and that PSB enforce compliance with s 59E more rigorously than in the past. This would include consideration being given to amending the Act to make a failure to impose the conditions contained in an authorisation an infringement offence.

7. That the Department propose amendments to s 59E to allow conditions to be changed as the situation requires, without further application by the practitioner, and to make it clear that the grant of a fresh authority extinguishes all previous authorities.

8. That where the conditions of authorisation require one nominated pharmacy, that pharmacy is provided with the conditions imposed.

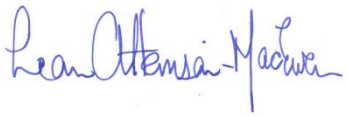
9. That PSB ensures that applications under s 59E(2) comply with the Act.

10. That DHHS takes steps to make sure that ADS runs its pharmacotherapy program in accordance with s 59E, and that consideration also be given to the appropriateness of continuing to administer that program under the current legislation.

11. That DHHS implement an education program aimed at both state and private hospitals to ensure that all relevant hospital employees are aware of their obligations under the Poisons Act.

12. That PSB and Tasmania Police implement a protocol around information sharing and data cleansing.

13. That PSB should, as far as is practicable, record and codify all of its current practices and policies to ensure consistency of use and ease of audit of decisions. In addition, PSB should ensure that this information is available to GPs.



Leon Atkinson-MacEwen
OMBUDSMAN
7 March 2013

APPENDICES

Appendix A – Extracts of Poisons Act 1971

Poisons Act 1971

PART VA - NOTIFICATION AND AUTHORISATION IN RELATION TO CERTAIN RESTRICTED SUBSTANCES AND NARCOTIC SUBSTANCES

59A. Interpretation of Part

In this Part –

make available includes prescribe, supply or authorise to be supplied;

notifiable restricted substance means a restricted substance that is declared by the Minister, by order, to be a notifiable restricted substance for the purposes of this Part;

prescribed period means a period that is declared by the Minister, by order, to be the maximum period for which a narcotic substance or a specified substance may be made available for continuous use by a person without an authority issued under section 59E;

specified substance means a restricted substance that is declared by the Minister, by order, to be a specified substance for the purposes of this Part.

59E. Authority for making drugs available to certain patients

(1) The Secretary may, on an application made under this section in respect of any person (in this section referred to as "the patient"), authorise a medical practitioner, dentist or authorised nurse practitioner to make available a narcotic substance or a specified substance for the use of that person.

(2) An application under this section is to be in writing in a form approved by the Secretary and signed by the medical practitioner, dentist or authorised nurse practitioner by whom it is made.

(3) An application is to –

(a) specify the patient in respect of whom it is made; and

(b) state whether, in the opinion of the medical practitioner, dentist or authorised nurse practitioner the patient –

(i) is a drug-dependent person; or

(ii) is exhibiting drug-seeking behaviour; or

(iii) has a history of obtaining a notifiable restricted substance, a narcotic substance or a prohibited substance for a non-medical purpose, or of unlawful possession or unlawful supply of a notifiable restricted substance, narcotic substance or prohibited substance; and

(c) contain such other information relating to the medical history and treatment of the patient as the Secretary requires.

(4) An authority given under this section in respect of a patient is to specify –

(a) the name of the narcotic substance or specified substance; and

(b) the amount of the substance to be made available; and

(c) the period during which the authority is to be in force; and

(d) any other substances which must not be made available in conjunction with the narcotic substance or specified substance; and

(e) the conditions under which, or the circumstances in which, the substance may be made available.

(5) An authority given under this section is to be in writing signed by the Secretary but, in a case of emergency, may be given orally.

(6) An authority given orally is to be confirmed in writing as soon as practicable after it is given.

(7) An authority given under subsection (1) also authorises a medical practitioner or dentist, who is in the same medical practice or dental practice as the person authorised, to make the substances available for the use of the patient in accordance with the terms of the authority.

Relevant definitions in the Poisons Act 1971

3. Interpretation

(1) In this Act, unless the contrary intention appears –

authorised nurse practitioner means a nurse practitioner authorised under section 25B;

dentist means a person registered under the Health Practitioner Regulation National Law (Tasmania) in the dental profession as a dentist, except in section 36 and Parts V

and VA in which case the dentist must be present in Tasmania and acting in the course of dental practice in Tasmania;

drug-dependent person means a person who –

(a) has acquired, as a result of the repeated administration of drugs of dependence, an overpowering desire for their continued administration; or
(b) has a condition such that the cessation of the administration of a drug of dependence, or the inability to obtain such a drug, is likely to cause him or her to exhibit signs of mental or physical distress or disorder; or
(c) exhibits drug-seeking behaviour that suggests impaired control as a result of the person's continued use of drugs of dependence; or
(d) consumes or uses a drug of dependence contrary to the prescribing practitioner's instructions;

drug of dependence means a substance listed in Schedule 8 or Schedule 9 to the Poisons List and includes any substance or class of substances that the Minister declares by order to be a drug of dependence but does not include any substance or class of substances that the Minister declares by order not to be a drug of dependence;

drug-seeking behaviour has the meaning given by section 4;

medical practitioner means a medical practitioner, except in section 36 and Parts V and VA in which case the medical practitioner must be present in Tasmania and acting in the course of medical practice in Tasmania;

narcotic substance means a substance that is, for the time being, specified in Schedule 8 to the Poisons List;

nurse practitioner means a person registered under the Health Practitioner Regulation National Law (Tasmania) in the nursing profession who is endorsed by the Nursing and Midwifery Board of Australia to practise as a nurse practitioner, except in section 36 and Parts V and VA in which case the nurse practitioner must be present in Tasmania and acting in the course of nurse practitioner practice in Tasmania;

pharmaceutical chemist means a person registered under the Health Practitioner Regulation National Law (Tasmania) in the pharmacy profession but does not include a person who holds provisional, student or non-practising registration in that profession;

Poisons List means Part 4 and Appendix C of the Uniform Standard adopted under section 14, as amended in its application to Tasmania under that section from time to time;

restricted substance means a substance that is, for the time being, specified in Schedule 4 to the Poisons List;

scheduled substance means a substance that is, for the time being, specified in any of the schedules to the Poisons List;

Secretary means the Secretary of the Department;

treatment centre means a treatment centre within the meaning of the *Alcohol and Drug Dependency Act 1968*;

Uniform Standard means –

(a) the Standard for the Uniform Scheduling of Medicines and Poisons, of the Commonwealth, published by the Australian Government under the *Therapeutic Goods Act 1989* of the Commonwealth; or
(b) any similar standard published in substitution for that standard; or
(c) if the standard or a standard published in substitution for that standard, has been amended under that Act, that standard as so amended.

4. Meaning of drug-seeking behaviour

For the purposes of this Act, a person is taken to exhibit drug-seeking behaviour in respect of a drug of dependence if there is reason to believe that –

(a) he or she is seeking to obtain a drug of dependence for the purpose of selling or supplying it to another person; or
(b) he or she is seeking to obtain a drug of dependence for a non-medical purpose; or
(c) as a result of the administration to him or her of the drug, he or she exhibits –

    (i) impaired ability to manage properly the use of any such drug; or

    (ii) behaviour which suggests such impaired ability; or

(d) failure to obtain drugs of dependence for a non-medical purpose is likely to cause the person to exhibit signs of mental or physical distress or disorder.

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