Investigation report

Undoing the knots constraining medicine regulation in Queensland

November 2016

Office of the HEALTH OMBUDSMAN

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Investigation report: Undoing the knots constraining medicine regulation in Queensland

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About this report

This report has been prepared by Mr Leon Atkinson-MacEwen, the Health Ombudsman for Queensland, outlining his investigation into the regulation of the prescribing and dispensing of schedule 8 medicines in Queensland.

Acknowledgments

I would like to acknowledge and express my appreciation to all of the organisations that took the time to provide me with information and submissions as part of this investigation. Seeking the views of the key stakeholders is a central element of any investigation and the material provided was invaluable during my deliberations.

In particular, I would like to acknowledge the support and cooperation of individuals within Medicines Regulation and Quality in the Queensland Department of Health. These individuals contributed extensively to this investigation, providing background information and advice, facilitating visits, meeting regularly with my staff and answering all questions and requests for information cooperatively. Medicines Regulation and Quality have a very broad remit and the comments and recommendations in this report are in no way to be seen as a criticism of the staff.

Executive summary

In late 2014 and early 2015, while undertaking a number of investigations into complaints made to my office, I noted allegations relating to prescribing and dispensing discrepancies which displayed common trends. During the course of these investigations, I sought information and comment from stakeholders, in particular Medicines Regulation and Quality in the Queensland Department of Health and the Australian Health Practitioner Regulation Agency.

During my investigations, I became aware of actions undertaken by Medicines Regulation and Quality which I considered raised concerns about the timing and adequacy of regulatory actions and of the dissemination of information to other relevant regulatory bodies. In particular, I was concerned about what appeared to be significant delays in taking appropriate action.

As a result, I commenced an own-motion systemic investigation under section 80(c) of the *Health Ombudsman Act 2013* to review the system responses to apparent inadequate, timely regulatory responses to prescribing and dispensing of schedule 8 medicines[1] that posed a risk to the health and safety of the public. The investigation also examined the broader aspects of the appropriateness and effectiveness of the Queensland regulatory system for scheduled medicines.

During the investigation, I sought input from a range of stakeholders including Medicines Regulation and Quality, Australian Health Practitioner Regulation Agency, Queensland Police Service, Office of the State Coroner, Pharmacy Guild of Australia, Pharmaceutical Society of Australia, Society of Hospital Pharmacists of Australia, and the 16 Hospital and Health Services in Queensland. I would like to thank those agencies that provided a submission and the agency staff, particularly those within Medicines Regulation and Quality, who assisted this investigation.

I also sought extensive material via my regulatory powers to ensure that I could produce an evidence-based report. My investigation identified that the regulatory framework for managing safe and appropriate access to schedule 8 medicines is complex, with responsibility shared across national and state levels and across multiple agencies. In Queensland, prescribing and dispensing is primarily regulated by Medicines Regulation and Quality in the Queensland Department of Health, which has legislative responsibility under the *Health Act 1937* and its subordinate legislation[2] for monitoring the prescribing, dispensing and use of schedule 8 medicines in Queensland. Medicines Regulation and Quality's regulatory role with regard to schedule 8 medicines is supplemented by a number of other agencies with related responsibilities including, but not limited to, my office, the Australian Health Practitioner Regulation Agency—on behalf of the national health practitioner boards—and the Queensland Police Service.

My examination of the framework for regulating schedule 8 medicines in Queensland has highlighted a number of areas of actual or potential risk. Of particular note, my investigation identified deficiencies in the coordinated inter-government department approach—in particular, the coordination of roles and

[1] Schedule 8 medicines are prescription only medicines that have specific restrictions placed upon their supply and use because of their dependence-forming nature and high levels of misuse. See chapter 2 for further information on schedule 8 medicines.
[2] Health (Drugs and Poisons) Regulation 1996; Health Regulation 1996

responsibilities between relevant agencies involved in regulating and responding to emerging prescribing and dispensing concerns with schedule 8 medicines. This lack of coordination underlies many of the risks associated with agency responses to prescribing and dispensing issues with schedule 8 medicines in Queensland.

My report makes 16 specific recommendations, aligned to areas of particular concern or risk, which propose suggested solutions and risk mitigation strategies. These recommendations are primarily focused on areas of legislative complexity, roles and responsibilities, policies and procedures, communication and collaboration, and real time prescription monitoring.

My investigation has identified that the lack of inter-agency cooperation is a significant contributory factor to system failures associated with the inappropriate prescribing or dispensing of schedule 8 medicines. As a result, I have recommended the creation of a committee to provide strategic oversight and facilitate inter-agency cooperation and coordination around responses to risks to the health and safety of the public associated with the prescribing, dispensing and use of schedule 8 medicines.

While this committee should play an oversight role, individual agencies will still be responsible for undertaking their different but interrelated functions. The lack of communication, coordination and collaboration around the sharing of relevant information between agencies identified in my investigation must be resolved as soon as possible as this is a key risk which compromises appropriate and effective system responses to emerging public safety concerns. To this end, I have recommended the development of formal arrangements between agencies to facilitate the exchange of information.

During my investigation, I also formed the view—as have other stakeholders across Australia—that the introduction of a real time prescription monitoring system would significantly assist in the effective and efficient monitoring of schedule 8 medicines in Queensland. It would also improve the management of the risks to public health and safety created by inappropriate prescribing or dispensing of such medicines. Consequently, I have recommended that the Director-General of the Department of Health commence a review, with the intent of implementing a real time electronic prescription monitoring system.

1. Introduction

In March 2015, I commenced an investigation under section 80(c) of the *Health Ombudsman Act 2013* into the appropriateness and effectiveness of the Queensland regulatory system for scheduled medicines as it applies to health services, in particular the prescribing and dispensing of schedule 8[3] medicines.

This report outlines the findings and recommendations arising from my investigation.

1.1 The role of the Health Ombudsman

As Health Ombudsman, I am an independent statutory officer appointed to protect the health and safety of the public. I am supported by the Office of the Health Ombudsman (OHO).

My functions include:

- receiving health service complaints and deciding on the relevant action to deal with them
- identifying and dealing with health service issues by taking relevant action, such as undertaking investigations or inquiries
- identifying and reporting on systemic issues in the way health services are provided, including their quality
- monitoring the performance of the Australian Health Practitioner Regulation Agency and the national health practitioner boards in their functions relating to the health, conduct and performance of registered health practitioners in Queensland
- identifying and communicating ways of providing health services that minimises and assists in resolving health service complaints
- reporting publicly on the performance of the health complaints management system in Queensland.

[3] See appendix 1 for further information on the scheduling of medicines in Australia.

1.2 Terms of reference

The principle objectives of the investigation were:

1. To identify, document and assess the appropriateness and effectiveness of agencies with key regulatory roles in monitoring and responding to concerns about the appropriate prescribing and dispensing of schedule 8 medicines within health services—taking into account current and proposed legislative and regulatory frameworks and best practice approaches.
2. To identify, document and assess the appropriateness of the regulatory responsibilities of and interactions between key agencies involved in monitoring and responding to concerns about the prescribing and dispensing of schedule 8 medicines.
3. To identify and assess the effectiveness of the current state-based prescription information management system for monitoring and responding to irregularities and non-compliance in prescribing and dispensing of schedule 8 medicines.
4. To identify and assess the effectiveness of current practices for monitoring, enforcing and improving the appropriate use of schedule 8 medicines.
5. To develop prioritised recommendations to support appropriate regulations, systems and processes for monitoring of prescribing and dispensing of schedule 8 medicines, with specific reference to
   - prescription information management systems
   - systems and processes
   - information exchange between key agencies
   - any other matter identified during the course of the investigation.

1.3 Regulatory framework

In Queensland, the management of schedule 8 medicines involves multiple agencies. This creates complexity and, in turn, increases risk. Malcolm Sparrow's broader view of minimising the harm associated with risk as *undoing harm*, and his associated analogy of *undoing knots* to understand and implement strategies to reduce harm, is useful when investigating the medicine regulation landscape in Queensland.[4]

Gavel and Sparrow remind us that when we are presented with a complex matter to resolve, rather than immediately jumping into action to sort it out, we must first consider the matter carefully and thoroughly. Once the structure of the problem is understood, a plan can then be formed to guide how we address each interrelated aspect of the matter (or *undo the knots*), until the matter itself is resolved.[5]

Focusing on the specific concerns related to medicine regulation in Queensland provides an opportunity to recognise specific patterns of actual or potential concern or risk. By closely investigating each concern

[4] Sparrow, M (2008), *The character of harms: operational challenges in control,* Cambridge University Press, Cambridge
[5] Gavel, G and Sparrow, M 2008, *Malcolm Sparrow on Controlling Risk,* interview, 1 may, Harvard Kennedy School, <https://www.hks.harvard.edu/news-vents/publications/insight/management/malcolm-sparrow>.

or risk (essentially *undoing* each of these knots), tailor-made solutions to effectively manage them—which also mitigate risk[6]—can be identified and implemented.

I have also been guided by the main objects of the *Health Ombudsman Act 2013*[7] and these have formed the regulatory framework of my investigation:

> *(a) to protect the health and safety of the public; and*
>
> *(b) to promote—*
>
> *(i) professional, safe and competent practice by health practitioners; and*
>
> *(ii) high standards of service delivery by health service organisations; and*
>
> *(c) to maintain public confidence in the management of complaints and other matters relating to the provision of health services.*

In addition, the following core principles underpinned my investigation and provided a lens through which I considered the issues:

1. Schedule 8 medicines are a necessary and beneficial part of safe clinical practice.
2. The role of regulation of schedule 8 medicines is to manage risk in order to protect the health and safety of the public.
3. The level of regulation should be commensurate with the risk posed by the regulated product.
4. A risk–benefits approach to the regulation of schedule 8 medicines that balances the need for maximising necessary medical access while minimising opportunities for misuse is appropriate.
5. Health professionals have a critical role in the safe and appropriate use of schedule 8 medicines.
6. The regulatory system must
    a. have the capacity to source and analyse data in a timely manner
    b. recognise and respond to risks in a timely manner.

The presentation of my report also draws on Sparrow's knot analogy where each of the specific areas of concern or risk identified from the information sources is identified as a named knot—for example, *The knot of legislative complexity*. Each knot is then discussed and analysed.

The recommendations arising from the analysis of each knot are then identified under the heading of *Undoing the knot*, and represent suggested solutions and risk mitigation strategies to address each of the identified specific areas of concern or risk.

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[6] Sparrow, M 2006, *The emergence of a risk-control approach to regulation*, Civil Service College Singapore, <https://www.cscollege.gov.sg/knowledge/ethos/ethos%20april%202006/Pages/The%20Emergence%20of%20a%20Risk-Control%20Approach%20to%20Regulation.aspx

[7] Section 3(1)

1.4 Limitations to scope

Monitoring and responding to the use and misuse of schedule 8 medicines occurs within a complex, multifaceted context. This includes:

- debates about the need for access to medicines for therapeutic purposes
- the level of services available for pain management and to assist individuals with drug dependence
- new and emerging drug treatments and off-label use of medicines—for example, medicinal cannabinoids
- the spectrum of effective strategies to minimise pharmaceutical drug misuse
- proposals for expanding prescribing scopes-of-practice to a broader range of health professions.

The resources available to me limited the scope and depth of my investigation. Consequently, while many issues are touched on in my report—as they provide context for my views—the investigation does not include:

- a comprehensive review of the epidemiology of schedule 8 medicines use and misuse
- detailed commentary on the different strategies to reduce misuse of pharmaceutical prescription medicines such as schedule 8 medicines
- detailed descriptions of the national regulatory and legislative environment which applies to medicines
- analysis of the appropriateness of the inclusion, or omission, of medicines in schedule 8 with the potential for misuse and dependence
- consideration of the adequacy of pain management and drug dependence treatment services within the state
- examination of the appropriateness of the range of professionals who have prescribing and dispensing rights for schedule 8 medicines
- prescribing and dispensing of schedule 8 medicines outside of the health sector—for example, by veterinary practitioners
- consultation with all stakeholders, such as private health facilities or environmental health units.

Further, a wide variety of stakeholders have an interest in the monitoring of, and responding to concerns about, the appropriate prescribing and dispensing of schedule 8 medicines within health services. Not all of these stakeholders engaged in my investigation to the same degree. Additionally, not all stakeholders capture relevant information or store it in an accessible way. For example, the Queensland Police Service indicated that their data systems could not provide information on the number of drug seizures involving schedule 8 medicines or the number of referrals they received from various agencies about prescribing or dispensing of schedule 8 medicines.

My investigation findings and recommendations must be viewed in this context.

1.5 Methods

On 17 March 2015, I informed the Director-General of the Department of Health of my intention to conduct an investigation into the regulatory system for scheduled medicines, in particular schedule 8 medicines, in Queensland.

I also gave notice of the investigation to, and requested or invited submissions from:

- Medicines Regulation and Quality (MRQ) in the Queensland Department of Health
- Australian Health Practitioner Regulation Agency (AHPRA)
- Queensland Police Service (QPS)
- Office of the State Coroner, which did not provide a submission
- Pharmacy Guild of Australia
- Pharmaceutical Society of Australia, which did not provide a submission
- Society of Hospital Pharmacists of Australia, which did not provide a submission
- the 16 Hospital and Health Services (HHSs) in Queensland, of which seven provided responses.

Further details of the actions taken and information and documents available to my staff are available in appendix 2.

1.5.1 Consultation on recommendations

Under the *Health Ombudsman Act 2013*,[8] I am required to consult with an entity where I propose to make a recommendation that the entity undertake particular action. Consequently, I provided the seven HHSs which provided an initial response, the Director-General of the Department of Health, MRQ, AHPRA and QPS with the opportunity to review and comment on my draft report, including the recommendations. I received responses from five HHSs, AHPRA and the Director-General of the Department of Health. An additional two HHSs that had not provided an initial submission also provided comment on the draft report at their own initiative. I considered these responses when finalising my report.

Further considerations in conducting this investigation are outlined in appendix 3.

[8] Section 86(5)

2. The schedule 8 medicines landscape in Queensland

Schedule 8[9] medicines are prescription-only medicines that have specific restrictions placed on their supply and use because of their dependence-forming nature and high levels of misuse.[10]

Schedule 8 medicines include a range of pharmaceutical drugs such as central nervous system stimulants and some benzodiazepines, but most notably pharmaceutical opioids[11] used for very strong pain relief (morphine) or to treat drug dependence (methadone).

Table 1 Major schedule 8 medicines

Drug class	Drug type	Brand names	Clinical indication
Opioid analgesics	Buprenorphine/ naloxone HCl	Suboxone	Pain relief
	Buprenorphine	Norspan	
	Codeine 30mg		
	Fentanyl	Durogesic, Denpax, Dutran, Fenpatch	
	Hydromorphone	Dilaudid	
	Methadone	Physeptone	
	Morphine	MS Contin	
	Oxycodone	Endone, Oxynorm (immediate release) , Oxycontin (sustained release)	
Benzodiazepines	Alprazolam	Alprax, Kalma, Xanax	Anxiety, panic attacks, sleeping disorders, alcohol and drug withdrawal, short term treatment of depression disorders
	Flunitrazepam	Hynodorm, Rohypnol	
Psychostimulants	Dexamphetamine	Sigma	Attention deficit hyperactivity disorder (ADHD), narcolepsy
	Methylphenidate	Ritalin	

According to data supplied by MRQ, increases in the number of scripts for schedule 8 medicines per capita has been quite pronounced in Queensland. The number of scripts dispensed per 100,000 population has increased by almost half (49 per cent) from 29,282 to 43,323 in the five years from 2010 to 2014.[12]

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[9] See appendix 1 for further information on the scheduling of medicines in Australia

[10] *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSMP; legally referred to as the *Poisons Standard)*. Most current version SUSMP No.6, 2015; The Poisons Standard is made under paragraph 52D(2)(b) of the *Therapeutic Goods Act 1989*

[11] Opiates derived from opium, as well as synthetic opioids

[12] MRQ submission.

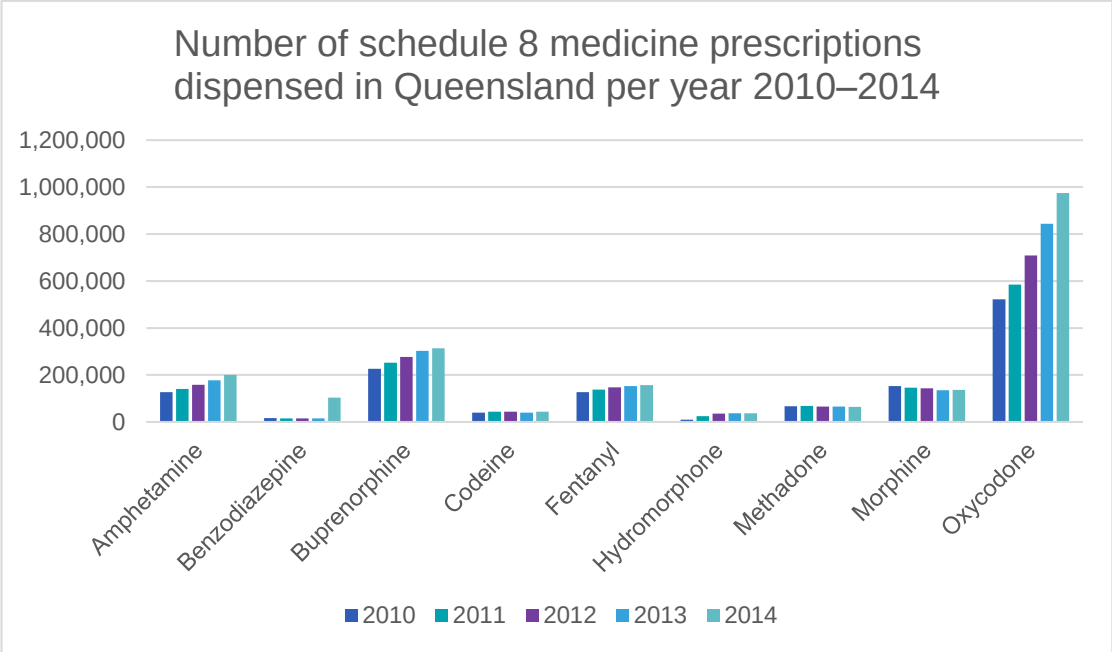

Figure 1 Number of schedule 8 medicine prescriptions dispensed in Queensland per year 2010–2014

2.1 Medicines Regulation and Quality

The regulatory framework for managing safe and appropriate access to schedule 8 medicines is complex, with responsibility shared across national and state governments and between multiple agencies.

In Queensland, the landscape is dominated by MRQ, which sits within the Chief Medical Officer and Healthcare Regulation Branch in the Queensland Department of Health. MRQ has primary legislative responsibility under the *Health Act 1937* and its subordinate legislation[13] for monitoring the prescribing, dispensing and use of schedule 8 medicines in Queensland.

According to MRQ,[14] the purpose of medicines legislation in Queensland is to promote and protect the health and safety of the public by:

- restricting access to medicines to people who have a need to use the medicine for a therapeutic, industrial or other purpose
- requiring people who use medicines to have competencies and to be accountable for their safe and effective use
- maintaining the quality of medicines through the supply chain
- promoting safe and effective use of medicines by consumers.

[13] Health (Drugs and Poisons) Regulation 1996; *Health Regulation 1996*
[14] Medicines Regulation and Quality. Medicines Compliance Strategy

2.1.1 Health Act 1937

The *Health Act 1937* provides for the establishment, maintenance and regulation of a system of licences for manufacturers, wholesalers and sellers of drugs and poisons, as well as providing for the labelling of medicines and poisons.

The *Health Act 1937* also grants investigative and related powers to the Department of Health chief executive[15] and delegates to enforce subordinate legislation such as the Health (Drugs and Poisons) Regulation 1996, and for those delegates to take various actions—for example, entering premises to search for schedule 8 medicines.

The *Health Act 1937* also creates various offences, such as failing to provide information, and penalties associated with committing any of those offences.

2.1.2 Health (Drugs and Poisons) Regulation 1996

The Health (Drugs and Poisons) Regulation 1996 provides a wide range of controls over the manufacture, packaging, labelling, storage, prescription, dispensing, sale, supply and use of substances listed in the *Poisons standard*[16] in order to prevent or reduce accidental, negligent or intentional misuse of medicines.

In particular, the Health (Drugs and Poisons) Regulation 1996 restricts the possession and supply of medicines by specifying who can perform which actions—such as obtain, possess, administer, prescribe, dispense, supply—with which categories of medicines. These restrictions generally flow from the schedule in which a medicine is included in the *Poisons standard*. These restrictions are set out in a framework of implicit and explicit approvals, also known as endorsements[17] and authorisations.[18]

Health professionals have implicit approval to undertake certain activities involving schedule 8 medicines based on their membership of a particular profession.[19] For example, doctors are authorised to obtain, possess, administer, prescribe, dispense, supply and provide instructions to administer or supply a schedule 8 medicine to the extent necessary to practice medicine without obtaining any explicit approval to do so.

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[15] The chief executive is a placeholder for the top executive in the Queensland Department of Health.
[16] *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSMP; legally referred to as the *Poisons Standard)*. Most current version SUSMP No.6, 2015; The Poisons Standard is made under paragraph 52D(2)(b) of the *Therapeutic Goods Act 1989*
[17] Endorsement means any of the following an authority, an approval, a drug licence, a wholesale representative licence, a poisons licence, a cyanide permit, a strychnine permit. Appendix 9. Health (Drugs and Poisons) Regulation 1996
[18] Authorisation is the authority a person has under the Health (Drugs and Poisons) Regulation 1996 because of the person's occupation or because the person holds an office to perform a stated act – such as possess, obtain, prescribe, administer, sell, – involving a controlled drug i.e. schedule 8 medicine. Appendix 9. Health (Drugs and Poisons) Regulation 1996
[19] Chapter 2, Part 2, Health (Drugs and Poisons) Regulation 1996

Despite this overarching approval, under specific high-risk circumstances, health professionals are required to obtain explicit approval prior to prescribing schedule 8 medicines. These circumstances include:

- treatment of drug-dependent[20] people[21]
- treatment of a patient with any *specified condition drug*, such as amphetamines, for a condition other than narcolepsy or brain damage or ADHD in a child aged between 4 and 18 years[22]
- lengthy treatment of a person with a schedule 8 medicine—i.e. for more than eight weeks.[23]

In these circumstances, authorised prescribers are required to complete a *Report to the chief executive*. Applications for approval are managed by MRQ.

In addition, authorised dispensers of schedule 8 medicines have specific reporting requirements to the chief executive of MRQ in relation to dispensing schedule 8 medicines under certain circumstances. These include when asked to dispense a schedule 8 medicine to a person either:

- in a quantity or volume greater than appears to be reasonably necessary
- more frequently than appears to be reasonably necessary.[24]

The Health (Drugs and Poisons) Amendment Regulation (No. 2) 2016, which came into effect on 1 June 2016, provides an interim framework for regulated access to medicinal cannabis. This followed the re-scheduling of botanical cannabis products and botanically-derived cannabis extracts from schedule 9 poisons to schedule 8 medicines.

The Regulation provides approvals to specified health professionals to obtain, possess, administer, prescribe, dispense, supply and provide instructions to administer or supply medicinal cannabis. While the requirements that apply to health professionals outlined in this Regulation are similar to those that apply to other schedule 8 medicines, they have been modified slightly. For example, pharmacists are not required to obtain a dispensing approval for medicinal cannabis products.

2.1.3 Health Regulation 1996

The Health Regulation 1996 imposes controls over the manufacturing of medicines and poisons that relate to good manufacturing practices, as well as the advertising and labelling of substances and devices that are used for, or in connection with, a therapeutic purpose. It also sets requirements in relation to the dispensing of medicines and poisons at a pharmacy.

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[20] The *Health Act, 1937 (Qld)* has the following definition of drug dependent person—*drug dependent person* means a person:
(a) who, as a result of repeated administration to the person of controlled or restricted drugs or poisons
(i) demonstrates impaired control; or-
(ii) exhibits drug-seeking behaviour that suggests impaired control over the person's continued use of controlled or restricted drugs or poisons; and
(b) who, when the administration to the person of controlled or restricted drugs or poisons ceases, suffers or is likely to suffer mental or physical distress or disorder.

[21] s122, Health (Drugs and Poisons) Regulation 1996

[22] s78, Health (Drugs and Poisons) Regulation 1996

[23] s120, Health (Drugs and Poisons) Regulation 1996

[24] Sections 84(10) and 84A(4), Health (Drugs and Poisons) Regulation 1996

2.2 Other agencies

MRQ's regulatory role with regard to schedule 8 medicines is supplemented by a number of other agencies with related responsibilities including, but not limited to:

- public health units from HHSs
- AHPRA and national health practitioner boards
- Queensland Police Service
- my office (see section 1.1).

2.2.1 Public health units

There are 11 public health units located in HHSs across Queensland that deliver services as specified in their respective service agreements, including public health regulatory monitoring, enforcement and compliance activity.

Public health units have responsibility for actively monitoring, enforcing and promoting compliance with the *Health Act 1937* and Health (Drugs and Poisons) Regulation 1996 on behalf of the Department of Health. Generally, the delineation of responsibility with the Department of Health is defined by policy/work instructions and chief executive delegation.

Public health units also monitor and enforce a range of other Acts and their subordinate legislation, including the *Public Health Act 2005, Food Act 2006, Radiation Safety Act 1999, Tobacco and Other Smoking Products Act 1998, Pest Management Act 2001* and *Water Fluoridation Act 2008*.

2.2.2 Australian Health Practitioner Regulation Agency and national health practitioner boards

AHPRA provides administrative support to the 14 national health practitioner boards including:

- managing registration and renewal practices for health practitioners, including endorsements to prescribe medicines
- managing complaints and investigating health practitioners if they have reason to believe:
  - the practitioner has, or may have, an impairment—for example, a substance misuse disorder
  - the way the practitioner practises or their conduct is or may be unsatisfactory—for example, involving unlawful or inappropriate prescribing or dispensing of medicines.

National health practitioner boards recognise a practitioner's competence to undertake certain behaviours involving medicines—such as prescribing and dispensing—through either:

- recognition that the primary qualification is sufficient to allow prescribing and/or dispensing medicines as an inherent part of the scope of practice for that profession—for example, general practitioners, dentists, midwives
- recognition via an endorsement to prescribe medicines, as currently exists for some registered professions—such as nurse practitioners—in accordance with section 14 and section 94 of the *Health Practitioner Regulation National Law* (the National Law).[25]

The endorsement of a health practitioner's registration under the National Law indicates that the practitioner is *qualified* for one or more of the following—to administer, obtain, possess, prescribe, sell, supply or use the scheduled medicines or class of medicines—as specified in the endorsement, but does not *authorise* the practitioner to do so.[26]

National health practitioner boards have the power to take action to restrict a registered health practitioner's use of scheduled medicines should a board reasonably believe that:

- the practitioner's conduct, performance or behaviour with regard to these medicines poses a serious risk
- the way the practitioner practices is or may be unsatisfactory
- the practitioner's professional conduct is or may be unsatisfactory
- the practitioner has an impairment.

Professional standards

National health practitioner boards also develop standards, codes and guidelines practitioners must meet, including those relating to the safe and quality use of medicines.[27] Professional standards specify the level of behaviour that is reasonably expected of a health practitioner in their professional conduct and practice—for example, in relation to the use of scheduled medicines.

Compliance by health practitioners with these standards is central to the effective operation of regulations within the Health (Drugs and Poisons) Regulation 1996, which are designed to restrict access to medicines to only those people who have a need to use them for a therapeutic purpose.

By mandating that schedule 8 medicines can only be accessed via specified health practitioners, there is a presumption that prescribers and dispensers of medicines play a unique role in mediating access to schedule 8 medicines.

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[25] Section 14, *Health Practitioner Regulation National Law (Queensland) 2014*
[26] The authorisation of a health practitioner to administer, obtain, possess, prescribe, sell, supply, or use scheduled medicines in Queensland is provided for in the Health (Drugs and Poisons) Regulation 1996.
[27] A number of other professional groups such as the Royal Australian College for General Practice and the Pharmaceutical Society of Australia also produce guidance documents to support safe, quality health care that include coverage of medicine safety. See appendix 4 for list.

2.2.3 Queensland Police Service

The role of the QPS involves:

- investigating matters that may, according to the *Criminal Code Act 1899* and the *Drugs Misuse Act 1986,* amount to unlawful pharmaceutical drug possession and supply and/or operation of a clandestine drug laboratory
- making decisions about whether these matters proceed to court for action against the alleged offenders
- informing other agencies—such as my office—of any relevant charges, convictions or investigations relating to unlawful pharmaceutical drug possession and supply.

2.2.4 Office of the Health Ombudsman

My office investigates matters involving a serious risk to the health and safety of the public including:

- professional misconduct, unprofessional conduct or unsatisfactory professional performance on the part of a health practitioner—including the misuse or abuse of schedule 8 medicines or prescribing or dispensing of schedule 8 medicines at a lesser standard than that which might be reasonably expected by the public or professional peers
- the diversion of schedule 8 medicines within a health service.

Further information on the regulatory framework for schedule 8 medicines is provided in appendix 1.

3. Knot 1—Legislative complexity

My investigation sought feedback from stakeholders regarding the impact of the current legislative and regulatory framework as it applies to health services—in particular the prescribing and dispensing of schedule 8 medicines.

Many of the submissions I received from stakeholders identified specific concerns relating to the *Health Act 1937*, the Health (Drugs and Poisons) Regulation 1996 and the Health Regulation 1996.

I consider the following issues highlight my specific concerns—and those of stakeholders—regarding the current legislative context.

3.1 Legislative limitations

I received seven submissions from HHSs responding to my invitation to contribute to this investigation, of which there were a number of common criticisms in relation to legislative controls surrounding schedule 8 medicines management.

Firstly, the legislation was considered to be open to interpretation or ambiguous. One HHS stated:

> *The legislation is unclear or hard to interpret by staff on the ground—every hospital has to rewrite the requirements of legislation into a procedure that hospital staff can follow.*

A response provided by another HHS supports this, explaining:

> *The formation of separate HHS has led to a diminution of an understanding of the Qld legislation, with some advice provided that the HHS have the authority to develop procedures on how the HHS interprets the legislation.*

Another HHS noted that:

> *QH [Queensland Health]/MRQ are not permitted due to legal privilege to provide HHS with legal opinions of the Health Act 1937 and subordinate legislation that directly impact on interpretation and investigation.*

Secondly, the prescriptive wording of the *Health Act 1937* and its associated regulation was commonly considered to limit the capacity of HHSs to adapt emerging technologies with contemporary routine clinical practices. A number of examples provided by HHSs of issues the legislation has been slow to respond to include:

- the use of electronic signatures on prescriptions
- electronic clinical information systems
- electronic systems limiting access to controlled drug storage
- use of automated dispensing machines
- technologies such as fingerprint and retina scanning for identification purposes.

One HHS stated:

> *Currently, provision for accepting such technologies occurs on a case by case basis and can be open to variance in interpretation and application under the current framework*.

For example, the Health (Drugs and Poisons) Regulation 1996[28] requires controlled drugs to be kept in a receptacle that complies with appendix 6 of the Regulation—a seven page specification which describes the minimum requirements for controlled drug receptacles. If an institution's receptacle does not comply with the minimum requirements—for example, an electronic system limiting access to controlled drug storage—in every case, an inspector must inspect the receptacle.[29]

The submission made by MRQ supported the criticisms made by HHSs, referring to the present legislation's 'inability to accommodate electronic prescribing and dispensing in either the community or the hospital situation'. The Queensland branch of the Society of Hospital Pharmacists of Australia identified similar concerns in their submission.

A third limitation of the Queensland drugs and poisons legislation and regulation identified by HHSs was the failure of the legislative framework to support the expansion of prescribing rights to a broader range of health professionals. The need to improve health system effectiveness and efficiency, in combination with workforce shortages that may limit access to medicines, make the need to develop and support non-medical practitioner prescribing models a key challenge for the health system that needs to be addressed.

Another limitation of the legislative framework identified by HHSs is the current inability of public health units to issue penalty infringement notices/fines for breaches of the *Health Act 1937* and its subordinate legislation, unlike for other similar legislation (such as the *Food Act 2006, Radiation Safety Act 1999, Tobacco and Other Smoking Products Act 1998, Pest Management Act 2001* and *Water Fluoridation Act 2008)*. This significantly limits the ability of public health units to effectively and efficiently enforce the *Health Act 1937* and Health (Drugs and Poisons) Regulation 1996.

3.2 Offences and charges preferred

The QPS submission emphasised the complexity of the current regulatory framework from an enforcement perspective. This is illustrated by conduct that constitutes an offence under both the Health (Drugs and Poisons) Regulation 1996 and the *Drugs Misuse Act 1986*.

For example, under the Health (Drugs and Poisons) Regulation 1996, it is a *simple offence* to possess, supply, manufacture, dispense, sell or otherwise deal with schedule 8 medicines, attracting maximum penalties of 80 penalty units.[30] However, the *Drugs Misuse Act 1986* provides for criminal penalties that include terms of imprisonment for the unlawful possession, supply, manufacture or trafficking of dangerous drugs. Dangerous drugs are those listed in schedule 1 or 2 of the Drugs Misuse Regulation 1987 or those that fall under the extended definitions of a dangerous drug referred to in

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[28] Section 118(1)(a)
[29] Section 118(1)(b)
[30] As at 1 July 2015, the penalty unit value in Queensland is $117.80. Maximum penalty under the Health (Drugs and Poisons) Regulation 1996, per offence, is currently $9424

section 4 of the *Drugs Misuse Act 1986*. A number of schedule 8 medicines are contained in schedule 2 of the Drugs Misuse Regulation 1987 making them dangerous drugs.

Therefore, unlawful possession, supply or manufacture of schedule 8 medicines may constitute both a simple offence under the Health (Drugs and Poisons) Regulation 1996 and a criminal offence under the *Drugs Misuse Act 1986*. Moreover, depending on the nature and severity of the practitioner's behaviour with regard to schedule 8 medicines, AHPRA and I can also take action against health practitioners that do not comply with the appropriate regulations.

I am of the view that clarification is required regarding the interrelations of the offences contained within the relevant legislation and the scope and powers of my office and the national boards.

Additionally, the QPS submission noted that the way in which charges are brought and offences recorded by the QPS can vary between officers. Under current procedures, the QPS is reliant on individual police officers without pharmaceutical training to identify and record specific medicines accurately in the Queensland Police Records and Information Management (QPrime) system in order to obtain clear data about offences. The medicines can include unpackaged tablets and medicines with multiple brand names and street names, resulting in a variety of names under which the medicines are recorded. The knowledge and ability of officers to identify that a medicine is both a schedule 8 medicine under the Health (Drugs and Poisons) Regulation 1996 and a dangerous drug under schedule 2 of the Drugs Misuse Regulation 1987 is a significant factor in identifying and preferring charges.

While acknowledging that it is difficult to classify illicit, non-marketed drugs that are rarely single component products, AHPRA noted that accepted descriptors for marketed medicines, including generic names, trade names and drug strengths, already exist and the use of these by the QPS for the identification of these drugs would be beneficial. The establishment of a reliable system for the recording of pharmaceutical medicines seized by police officers may assist communication between agencies, including facilitating a comprehensive response to enforcement.

I note also that during my investigation, one HHS commented that the Department of Health is of the view that there is a conflict of interest for staff of public health units in monitoring and enforcing the *Health Act 1937* and its subordinate legislation, which contributes to a gap in enforcement in public facilities. The role of public health units is discussed further in section 4.2.

3.3 Disclosure

The QPS raised concerns with me regarding the effectiveness of current criminal history disclosure requirements which aim to manage risk by requiring health practitioners and Queensland Health employees who have been charged with or convicted of a criminal offence to disclose their criminal record to registration boards or prospective employers.

This concern was mirrored by HHSs, with one HHS stating:

> *…there is limited ability for the HHS to confidently probe the drug misuse history of a previously registered health professional via AHPRA. For example a pharmacist decides not to re-register, rather than being investigated by AHPRA after being charged with a simple*

offence (community service, no conviction recorded) in relation to schedule 8 medicine misuse. They subsequently apply for a position at a different health service to work as an unregistered pharmacy assistant)…[it] is unclear if the systems in place would adequately identify this type of situation and prevent further access to medicines.

On behalf of the national health practitioner boards, AHPRA conducts criminal history checks during the registration process to ensure practitioners are suitable to practice in Australia. In addition, when a practitioner first applies for registration, AHPRA requires applicants to disclose their criminal history in all countries. When practitioners renew their registration, they must also disclose any changes to their criminal history. In addition, all registered health practitioners must inform the relevant national board[31] if:

- they are charged with an offence punishable by 12 months imprisonment or more
- they are convicted or found guilty of an offence punishable by imprisonment in Australia and/or overseas
- their billing privileges are withdrawn or restricted under the *Medicare Australia Act 1973* because of the practitioner's conduct, professional performance or health
- their authority under a law of a state or territory to administer, obtain, possess, prescribe, sell, supply or use a scheduled medicine or class of scheduled medicines is cancelled or restricted.

Similarly, all Queensland Health employees are required to notify their supervisor if they are charged or convicted of a criminal offence.[32]

As mentioned previously, under the Health (Drugs and Poisons) Regulation 1996, offences in relation to the prescribing and dispensing of scheduled medicines are considered simple offences which are punishable by penalty units and do not have a penalty involving imprisonment. Therefore, there is no obligation on the part of a practitioner or employee to notify either a national board or an employer if they are charged or convicted with offences under the Health (Drugs and Poisons) Regulation 1996.

In his response to my draft report, the Director-General of the Department of Health advised that in practical terms, if prosecution was to have occurred leading to penalty unit punishment, the Department of Health would also withdraw approval to prescribe or dispense, which would mean that the practitioner would be obliged to report it to their national board within seven days.

In its response to my draft report, AHPRA noted that under the National Law, the onus is on the individual health practitioner to report to AHPRA and this only applies after a cancellation or restriction is imposed by the state authority or a criminal offence. Until such time, AHPRA may have no advice that there is an investigation into the activity of a registered practitioner.

Of particular concern is the ineffectiveness of these disclosure measures in alerting AHPRA, my office and the Department of Health to the potential risks practitioners and employees may present either to themselves—because of a health impairment—or to the health and safety of the public.

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[31] Pursuant to s130 of the *Health Practitioner Regulation National Law (Queensland) 2014*

[32] Employees to Notify Supervisor if Charged with or Convicted of an Indictable Offence. (2014). Department of Health Policy Number: E4 - QH-POL-127. Accessed at https://www.health.qld.gov.au/system-governance/policies-standards/doh-policy/policy/qh-pol-127.pdf

This is of particular concern to me as protecting the health and safety of the public is a primary function of my office. A number of matters currently under investigation within my office relate to numerous alleged breaches of the Health (Drugs and Poisons) Regulation 1996 by health practitioners and evidence a sometimes significant risk to the health and safety of the public. It is imperative that my office is notified where practitioners are charged with or convicted of offences under the Health (Drugs and Poisons) Regulation 1996, as this would allow me to work closely with the national health practitioner boards to ensure that both the practitioner and the risk to the health and safety of the public are appropriately managed.

I note that the QPS has recently implemented practices to identify health professionals subject to charge or investigation and for the Queensland Health Police Liaison Unit to proactively report to AHPRA and my office when practitioners are identified as being the subject of a relevant investigation. This is a valuable initiative and should continue. It may be that there are also improvements required to the National Law in relation to the definition of *relevant events* to ensure such offences are reported to the appropriate agency.

3.4 New legislative framework

I am aware the Department of Health has proposed new legislation to protect 'the public from the health risks associated with inappropriate access to, and use of medicines, poisons and therapeutic goods' and to minimise 'the risk that medicines and poisons can be diverted for unlawful purposes'.[33]

I understand that the intention is to propose that parliament repeal the current legislation, including the *Health Act 1937*, the Health Regulation 1996 and the Health (Drugs and Poisons) Regulation 1996, and replace it with a new suite of legislation—a new medicines, poisons and therapeutic goods Act and Regulation.

Key objectives of the proposed legislation include:

- protecting the public from the health risks associated with inappropriate access to and use of medicines, poisons and therapeutic goods
- minimising the risk that medicines and poisons could be diverted for unlawful purposes
- adopting a contemporary approach to regulating medicines, poisons and therapeutic goods in Queensland that introduces a more responsive and outcomes-focussed regulatory framework
- enhancing consistency with national regulatory frameworks by implementing decisions of the Council of Australian Governments in relation to the regulation of medicines, poisons and therapeutic goods
- streamlining the regulatory controls governing medicines, poisons and therapeutic goods to reduce the associated regulatory costs for industry, consumers and government
- ensuring legislation accords with modern drafting practices and has sufficient regard to fundamental legislative principles.[34]

[33] Queensland Health. (2014) Background Paper – Consultation Draft of Medicines, Poisons and Therapeutic Goods Bill 2014.
[34] Queensland Health. (2015). Medicines, poisons and therapeutic goods in Queensland – explanation of the new regulatory regime.

I note that under the proposed new legislative framework, Queensland will continue to adopt the classification system for medicines and poisons outlined in the current *Poisons standard*. The proposed legislation also outlines the circumstances under which *eligible persons* will be able to perform regulated activities with scheduled substances because of their profession, occupation or position held within a hospital, nursing home, university or other institution.

I further note that the proposed Medicines, Poisons and Therapeutic Goods Bill 2015 will consolidate more than 50 separate offences about the manufacture, supply, possession and use of medicines identified in the existing legislation into seven key offences.

The proposed Medicines, Poisons and Therapeutic Goods Bill 2015 will also introduce the requirement for facilities such as hospitals, nursing homes and community pharmacies to develop and implement a scheduled substance management plan that addresses how they will meet relevant standards to ensure the safe and effective management of regulated substances.

I am strongly supportive of the objects[35] of the proposed Medicines, Poisons and Therapeutic Goods Bill 2015, in particular:

> *(c) to ensure persons who are given the authority to deal with the substances have the necessary competencies to do so safely.*

As the draft Regulations that will accompany the proposed Bill had not been released for consultation at the time of the drafting of this report, I am unable to comment on the adequacy or otherwise of the measures they contain to ensure that *eligible persons* have the necessary competencies to deal with scheduled medicines.

While I am supportive of innovative approaches to improve access to medicines, any extension of authority to new groups of people for prescribing, supplying and/or administering scheduled medicines must be accompanied by adequate training and education, as well as oversight.

I am also supportive of measures to reduce the regulatory burden and consider the introduction of scheduled substance management plans a suitable approach to regulating the risks associated with medicine management. Again, the proposed Bill provides limited detail about the requirements of these plans, with the specifics to be addressed through the accompanying Regulations. I consider that there is a strong need for a requirement for scheduled substance management plans to comply with current best practice standards and for any entity required to have a plan in place to be subject to regular compliance auditing.

Furthermore, in my view there are clear interrelations between the offences contained within the proposed legislation and the scope and powers of my office, particularly as they relate to *eligible persons*. Clarification over these interactions will be necessary to ensure efficiency and avoid unnecessary duplication between agencies.

I note that, following consultation on an earlier version of the proposed Bill, further consultation with stakeholders was undertaken in 2015. I consider it imperative that the Department of Health continue to

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[35] Section 4 Medicines, Poisons and Therapeutic Goods Bill 2015 (Qld)

consult extensively with stakeholders to ensure a co-ordinated, strategic response to the ongoing development and implementation of the regulatory system. This will be of particular importance upon the release of the Regulations that will accompany the proposed Bill. I understand that the Department of Health has committed to involving industry and professional organisations in a consultation process for the Regulations when they are released and encourage the inclusion of other agencies with overlapping regulatory responsibilities.

It is also important that the Department of Health take into account the issues raised by stakeholders in response to my call for submissions and identified in this report when finalising the new regulatory framework. For example, HHSs suggested that further restrictions on prescribers may be necessary to limit access to medicines through prescribing for themselves or family members. In a submission to my investigation, one HHS also noted that the proposed inclusion of the provisions of the *Pest Management Act 2001* and regulation in the draft Medicines, Poisons and Therapeutic Goods Bill 2015 will add another unnecessary layer of complexity to the legislation.

Further, I note that the new framework involves significant conceptual change as it moves to a contemporary risk management approach to regulation and, as such, will require ongoing education and communication with stakeholders.

3.5 Undoing knot 1

I recommend that the Director-General of the Department of Health:

1. Continues to actively consult with stakeholders on the proposed new framework for the regulation of medicines, poisons and therapeutic goods in Queensland, in particular in relation to the prescribing and dispensing of schedule 8 medicines.
2. Takes into account the issues identified in this report in his consideration of the proposed new legislation.
3. Ensures that the Department of Health works closely with stakeholders—including national health practitioner boards, QPS, professional associations and organisations such as the Private Hospitals Association of Queensland—following the introduction of the new medicines, poisons and therapeutic goods Act, to implement a tailored education program aimed at each stakeholder group to ensure all are aware of their obligations under the new legislation.
4. Ensures MRQ continues and strengthens its work with the QPS to ensure adequate guidance is provided to QPS officers about the misuse of scheduled medicines and the availability of various charges, as well as the practical consequences of bringing charges under a particular Act.
5. Considers recommending to the Queensland Minister for Health to propose at the next Australian Health Ministers' Conference that amendments are made to the National Law to require practitioners to disclose to their national board if the practitioner has been charged or convicted of an offence under drugs and poisons legislation, whether in a participating jurisdiction or elsewhere.

Responses to recommendations

In response to the draft report I provided to agencies for their review and comment, which included my proposed recommendations, the Director-General of the Department of Health advised that:

- consultation with stakeholders is planned for the new legislation (recommendation 1)
- the development of the new legislation will take the recommendations of this report into consideration (recommendation 2)
- the Department of Health intends to work with stakeholders to implement an education program to ensure stakeholders are aware of their obligations under the new Medicines, Poisons and Therapeutic Goods Act (recommendation 3)
- while not a formal written procedure, there is a strong and long-standing arrangement between MRQ and QPS, which includes annual QPS officer training for new recruits and regular provision of on-the-spot advice to QPS officers across Queensland in relation to the misuse of scheduled medicines and the availability of various charges (recommendation 4)
- recommendation 5 should be removed as he considered that this requirement is already met.

One HHS raised concerns about the compliance burden resulting from recommendation 5, stating:

> *There would be examples of simple breaches [of the Health (Drugs and Poisons) Regulation 1996] that don't impact on a person's registration status. The compliance with the proposed recommendation would be onerous…there is already a mandatory reporting requirement for all practitioners and employers under the National Law to AHPRA.*

I acknowledge that the current registration processes includes a number of screening questions to identify potential risks to safe and high quality practice. However, I am of the view that the current requirements do not adequately capture all regulatory activity that might suggest a potential risk to the health and safety of the public. I also note that additional disclosure requirements may provide a greater demand on health practitioners. Nevertheless, I consider the benefits of such an approach outweigh any addition pressures.

4. Knot 2—Roles and responsibilities

As recognised by MRQ in its submission, it is neither possible nor reasonable for any one of the agencies involved in the regulatory environment for medicines in Queensland to undertake all of the regulatory functions relating to schedule 8 medicines.

Successful achievement of the complex policy outcomes associated with safe and effective use of schedule 8 medicines requires the involvement of multiple agencies and necessitates effective cross-agency collaboration supported by appropriate governance arrangements.

In his response to my draft report, the Director-General of the Department of Health advised me that, as at 25 July 2016, MRQ was restructured, with some work functions removed and established in other areas of the Chief Medical Officer and Healthcare Regulation Branch. Of particular note is the separation of the surveillance and education functions of MRQ from the investigations function, which is now located in a separate unit (Medicines Compliance and Human Tissue Unit), and the separation of the administration of the legislation from the review and development of the legislation (now conducted by the Healthcare Legislation Improvement Unit).[36]

4.1 Medicines Regulation and Quality

As previously mentioned, MRQ has primary responsibility under the *Health Act 1937* and its subordinate legislation for monitoring the prescribing, dispensing and use of schedule 8 medicines in Queensland.

At the time of writing this report, MRQ had an allocation of 34 staff. The director of MRQ manages the team's four business groupings comprising:

- clinical policy (7 positions)
- medication safety (5 positions)
- surveillance and compliance (12 positions)
- data management and information systems (9 positions).

MRQ staffing levels by classification are shown in figure 2 below.

[36] See appendix 5 for details of new structure.

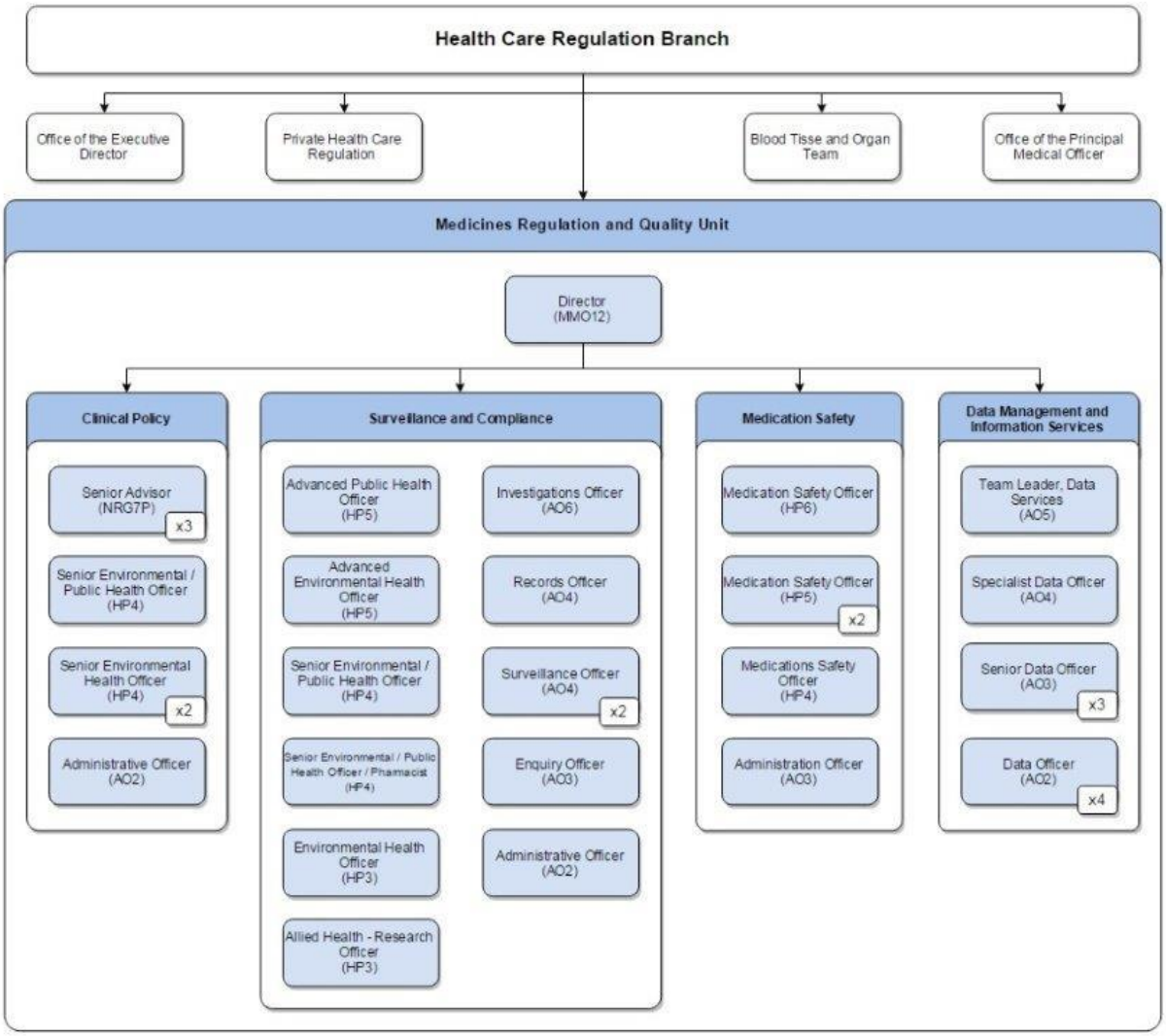

Figure 2 Medicines Regulation and Quality structure

It is evident from my examination of the relevant legislation and documentation provided in MRQ's submission, that MRQ undertakes a number of distinct, albeit interrelated, activities related to medicines and poisons generally, and schedule 8 medicines in particular.

These activities and functions can be grouped into four areas:

1. Administration of licences and approvals, including the Queensland Opioid Treatment Program.
   - MRQ staff undertake management of licences and approvals to manufacturers, wholesalers, individuals (including health practitioners) and other entities to manufacture, distribute, sell, provide treatment with, conduct research with, or use scheduled medicines and poisons.
   - MRQ also provide administrative oversight of the Queensland Opioid Treatment Program (QOTP), which provides opioid treatment through public clinics and private pharmacies.

2. Provision of clinical support and advice.
    - MRQ has responsibility for providing, via a confidential telephone enquiry service, clinical support and advice to health practitioners to ensure appropriate use of schedule 8 medicines.
3. Data processing, monitoring and analysis.
    - MRQ staff undertake processing of schedule 8 medicine prescription data from pharmacies, including data quality assurance, as well as surveillance and analysis of dispensing data to identify inappropriate use of schedule 8 medicines.
4. Enforcement of regulatory non-compliance.
    - MRQ staff undertake enforcement activity in situations of regulatory non-compliance, including investigation and prosecution of alleged offences under the Health (Drugs and Poisons) Regulation 1996.

4.1.1 Administration of licences and approvals

Under the Health (Drugs and Poisons) Regulation 1996, specific licences or approvals are required for a range of regulated activities, including but not limited to:

- treatment involving schedule 8 medicines including for a patient considered to be drug dependent[37]
- treatment of a patient with a schedule 8 medicine for a period exceeding eight weeks
- treatment with any *specified condition drug* other than for attention deficit disorder in a child or for treatment of narcolepsy
- a range of other activities with scheduled medicines.

In 2014, staff within the unit, among other work:[38]

- received and processed information on more than two million prescriptions for schedule 8 medicines from more than 1000 pharmacies
- managed more than 200 QOTP prescriber approvals
- managed more than 550 approvals[39] for treatment with any *specified condition drug* other than for attention deficit disorder in a child or for treatment of narcolepsy
- managed more than 750 approvals[40] for treatment of a patient considered to be drug dependent
- received more than 5000 reports[41] of treatment with a schedule 8 medicine for longer than 8 weeks.

[37] As per section 5 of the *Health Act 1937*
[38] MRQ submission.
[39] Section 78 of the Health (Drugs and Poisons) Regulation 1996
[40] Section 122 of the Health (Drugs and Poisons) Regulation 1996
[41] Section 120 of the Health (Drugs and Poisons) Regulation 1996

4.1.2 Provision of clinical support and advice

MRQ's telephone support and enquiry service is available 24 hours a day, seven days a week and provides information to health practitioners about medication safety and compliance with legislative requirements, including:

- patient status—such as the patient's schedule 8 medicine history, drug dependence status, participation in the QOTP and applicable current drug treatment approval
- regulatory requirements under the Health (Drugs and Poisons) Regulation 1996
- treatment involving schedule 8 medicines, including the QOTP.

All calls to the service are screened by the Alcohol and Drugs of Dependence Unit from the Metro North HHS, with more complex enquiries handled by the MRQ senior advisors during business hours. Senior advisors, who are clinical nurses, can give general advice to medical practitioners on pharmacotherapy issues.

In 2014, MRQ responded to more than 20,000 calls[42] on the telephone enquiry line, with the number of calls almost doubling since 2010 (up 85 per cent) and the vast majority (88 per cent) relating to queries about a patient's schedule 8 medicines history.[43]

While recognising the value of MRQ's telephone enquiry service, stakeholders noted that there was limited awareness of the service. Just as importantly, stakeholders observed that there were limitations on the information available to health professionals outside of normal business hours as more complex enquiries are handled by the MRQ senior advisors who are only available during business hours.

The perception of insufficient resourcing was reinforced in submissions received from the HHSs. One HHS stated:

> *It is questionable whether there is sufficient resourcing in the regulatory areas such as MRQ, Drug of Dependence Unit, as historically there was much more human resources and information available and the unit provided easy to understand resources…*

4.1.3 Data processing, monitoring and analysis

MRQ collates schedule 8 medicines dispensing data for the state via the Monitoring of Drugs of Dependence System (MODDS).[44]

Dispensing data is provided to MRQ by public and private dispensers within 14 days of the end of each month. This information captures all schedule 8 medicines dispensed as a result of individual and QOTP prescriptions, with the exception of schedule 8 medicines administered within hospital settings.

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[42] The number of 'calls' to the enquiry service is unable to be determined. Only calls related directly to patient-related issues will be recorded. General calls about legislation, licensing, investigation matters and compliance cannot be recorded so this figure would therefore be an underestimate of total calls received.
[43] MRQ submission.
[44] Controlled Drug Recording & Monitoring System – High Level Business Requirements Specification, 14 February 2014, v0.6, p.15

MRQ indicated that 50 per cent of dispensing data is visible in MODDS within two to three weeks of the dispensing event, although some data does not appear until as many as six weeks after the dispensing of the schedule 8 medication. This time delay hinders efforts to monitor and manage risks associated with the inappropriate and unsafe use of schedule 8 medicines.

In 2014, MRQ received and processed information on more than two million prescriptions for schedule 8 medicines from more than 1000 pharmacies.[45] MRQ staff also responded to more than 100 requests for information from external agencies including the QPS, Office of the State Coroner and AHPRA.

Monitoring

In order to guide their enforcement activity, MRQ monitors schedule 8 medicine dispensing information stored in MODDS to identify any concerns with non-compliance with regulatory requirements.

Based on designated criteria, the MRQ surveillance officer conducts regular reviews of the data captured in MODDS and retrieves lists of cases that involve potential non-compliance. MRQ undertakes regular reviews of their data against nine standard criteria known as surveillance alerts (see table 2).[46]

Table 2 Current Medicines Regulation and Quality schedule 8 medicine surveillance alerts

Alert name	Description	Relevant Health (Drugs and Poisons) Regulation 1996 requirement	Frequency	Threshold
Doctor shopping (regular* QOTP and report patients)	Identifies people who are consulting multiple doctors.	S122	Monthly	Greater than 5 doctors and 15 prescriptions in any 4 week period.
Ex-program getting schedule 8 medicine scripts	People previously in the QOTP obtaining schedule 8 medicines. Includes report, approval and program people.	s122	Monthly	Client on the QOTP within the last 5 years getting any schedule 8 medicines without an approval
Fentanyl surveillance	Patients being prescribed fentanyl patches.	s122	Monthly	Fentanyl >1 patch per day

[45] MRQ submission.
[46] MRQ submission

Alert name	Description	Relevant Health (Drugs and Poisons) Regulation 1996 requirement	Frequency	Threshold
High dose identification v1.0	Lists clients getting nominated *drug* in a three-month window. Can be filtered by classification (regular, report, or approval). Used to identify large daily drug amounts (mg/day) as well as high risk schedule 8 medicines (injectables and patches) being prescribed with no approval/report.	s78 s122	Monthly (rotating schedule 8 medicines each month)	Alprazolam >6mg/day Hydromorphone >80mg/day Methadone any with no report/approval Morphine >120mg/d Oxycodone >80mg/d Pethidine any with no report/approval Psychostimulants any with no report/approval
Doctors obtaining for family	Doctors prescribing schedule 8 medicines for family members.	s123	Every 2 months	No threshold
Schedule 8 medicines—Doctor self-prescribing	Doctor self-prescribing schedule 8 medicines for themselves.	s123	Every 2 months	No threshold
QOTP other drug v1.0	Client on the QOTP and being prescribed schedule 8 medicines.	s122	Every 2 months	No threshold
Non-program person WI v1.0	Non-program person getting QOTP drugs and not registered on the program.	s122	Every 4 months	No threshold
Non-program prescriber v1.0	Non-approved prescriber writing written instruction.	s122	Every 4 months	No threshold

*Regular refers to a person that does not a have treatment report or an approval.

Note: The usual threshold for doctor shopping is adjusted by surveillance officer dependent on the volume of cases returned and/or for particular focus on either volumes or types of drugs.

High dose Id threshold—No high dose threshold is set, usually highest volume prescribed of certain drug type is sufficient for further examination.

My investigation identified a range of limitations in the current criteria[47] MRQ uses to review the information in MODDS to identify potential regulatory non-compliance. For example:

- Examination of MRQ's surveillance alerts for the monitoring of dispensed prescriptions with a high daily drug dose indicates that it does not monitor high drug doses for *all* schedule 8 medicines every month but only either a targeted drug each month—for example, alprazolam—or psychostimulants as a group. This results in drug dosage for each targeted drug being actively monitored twice a year at the most.

  Feedback on the draft report

  - AHPRA commented that high dose identification is a blunt instrument in the absence of clinical data.
  - AHPRA also commented that discussion at the time of prescribing or seeking authority allows for the identification of the appropriateness or otherwise of higher doses.
  - AHPRA noted that it is not uncommon for patients to use combinations of appropriate drugs e.g. oxycontin and oxycodone, and it was unclear if current monitoring captured these risks.
  - The Director General of the Department of Health advised that the Department of Health does not consider more frequent monitoring would be an effective use of surveillance resources as a longer timeframe is required to identify patterns of prescribing.
  - The Director General further advised that there is no regulatory requirement in this regard, with no offence provisions for high dosing, with MRQ conducting this surveillance from a public health risk perspective.

    I am supportive of the need for public health surveillance and action to address potential drug misuse and abuse in this area, but am also of the view that this further serves to demonstrate the multiplicity of disparate functions and purposes that MRQ endeavours to deliver.

- While self-administration of schedule 8 medicines is prohibited under the Health (Drugs and Poisons) Regulation 1996,[48] my investigation identified that MRQ only review MODDS data every two months to detect prescriptions dispensed where the prescriber and recipient are the same. MRQ also stated that the nature of MODDS data is not conducive to clearly evidencing self-prescribing and self-administration of schedule 8 medicines. According to data supplied by MRQ in its submission, between 2010 and 2014, MRQ identified fewer than 10 health practitioners a year as self-prescribing.

  Feedback on the draft report

  - AHPRA submitted that self-prescribing is explicitly prohibited under the regulations and as such should be continuously monitored.
  - One HHS also stated that '…*prescribing a schedule 8 medicine for a family member was considered a euphemism in many cases for self prescribing*'.

[47] See table 2 for full list of current surveillance alerts.
[48] Section 123

- MRQ stated in their submission to me that the threshold for identifying cases for follow-up that involved prescription shopping patients—i.e. patients that were consulting multiple doctors to obtain prescriptions for schedule 8 medicines—is adjusted on a monthly basis if necessary by MRQ staff depending on the number of cases initially identified for potential follow-up. The use of inconsistent thresholds, depending on the volume of work, is concerning.

  Feedback on the draft report

  - The Director-General of the Department of Health advised that there is no accepted definition of doctor shopping and therefore no set criteria on which surveillance is conducted.
  - The Director General further advised that MRQ has been working towards establishing a robust definition of high-risk drug seeking behaviour in order to improve monitoring and to this end is engaged in a research venture with the University of Queensland, to define problematic drug seeking.

- MRQ indicated in its submission that it considered non-compliance with section 84A(4) of the Health (Drugs and Poisons) Regulation 1996—i.e. the requirement for a dispenser to report immediately to MRQ dispensing requests for schedule 8 medicines that appear to be for amounts more than reasonably necessary, or more frequently than reasonably necessary—'minor non-significant non-compliance' raising 'limited health and safety concerns'.[49] It is not clear to me why the failure of a dispenser to comply with their requirements in this area would be considered low risk given the evidence that schedule 8 medicines, in particular opioids, are commonly implicated in overdose deaths as evidenced in coronial findings from across the country.
- During my investigation, MRQ acknowledged that it does not routinely monitor compliance with section 120 of the Health (Drugs and Poisons) Regulation 1996—i.e. the requirement for a prescriber to notify MRQ if they are providing lengthy treatment (more than eight weeks) to a person with a schedule 8 medicine—due to structural limitations in developing appropriate and meaningful queries. MRQ also indicated in its submission to my investigation that its monitoring activities target high-risk patients and that in their view there is no evidence that long-term prescribing of schedule 8 medicines represents any significant health risk.
- My investigation identified that MRQ is unable to undertake any monitoring activities based on the type of practitioner involved. Prescribing of medicines by health professionals other than medical practitioners and dentists is not uncommon. Currently the optometry, podiatry and nursing and midwifery boards offer registrants the ability to gain an endorsement on their registration for the prescribing of scheduled medicines. MRQ is currently unable to monitor any trends that may emerge relating to a specific profession.

  Feedback on the draft report

  - The Director-General of the Department of Health advised that on a practical level
    - the prescribing of schedule 8 medicines is not in scope for optometrists
    - endorsed podiatrists do not have endorsement to prescribe schedule 8 medicines

[49] MRQ submission

- surgical podiatrists are limited to prescribing short acting oxycodone but there are very few practitioners in Queensland
- nurse practitioners can prescribe schedule 8 medicines and there are PBS items they can prescribe, however the majority of nurse practitioners are still employed in the public sector or other institutions
- eligible midwives do have schedule 8 medicines in their PBS list, however, the Health (Drugs and Poisons) Regulation 1996 does not allow prescribing of schedule 8 medicines.

I acknowledge that at this point in time, prescribing and dispensing of medicines may be predominantly undertaken by specific professions and that this report focuses on schedule 8 medicines. Nevertheless, as the scope of practice for many allied health roles is likely to expand in the future and includes prescribing and dispensing of schedule 4 medicines, misuse of which also have significant public health and safety implications, the ability to monitor by profession would be a desirable element of any monitoring program.

Business requirements and capacity

MRQ indicated during my investigation that the scope of the current surveillance activities undertaken on data within the MODDS system to identify potential non-compliance is the result of changes in business requirements and staffing capacity.

As previously mentioned, concerns were raised by stakeholders during my investigation over MRQ's capacity to fulfil its surveillance and investigatory functions. For example, QPS commented that it was:

> *…of the view that MRQ, who hold information on prescriptions, does not have sufficient resourcing, nor the intelligence capability to proactively analyse data in order to identify offences for referral to police, be it related to an individual, a prescriber or a pharmacy.*

One HHS referred to MRQ's role as providing 'passive surveillance' which 'doesn't assist in identifying over-prescribing of schedule 8 medicines'.

While I acknowledge that changing business requirements and resourcing may limit the ability of an organisation to respond to all regulatory non-compliance, I am of the view that key risks to regulatory outcomes and responses to these risks should be comprehensively identified and documented, along with the range of appropriate response options.

I recognise the limited resources available to MRQ, and, as a result, I consider the level of compliance monitoring undertaken by MRQ is reasonable within the limits of current resourcing. However, I am of the view that based on the information gathered during my investigation, the current scope and level of monitoring undertaken by MRQ in isolation is insufficient to protect the health and safety of the public. I note that the introduction of a real time prescription monitoring system has been suggested for some time as a method for improving capacity to monitor access to schedule 8 medicines. This is discussed further in section 7 of this report.

During my investigation, HHSs indicated that they consider MRQ's decision to restrict the role of public health units (PHU) in monitoring and analysing schedule 8 medicines information has contributed to the lack of capacity in this area. One HHS noted:

> *MRQs limited resources have come about due to their decision to restrict PHUs roles in this program area. PHUs used to have access to MODDS, provide advice to doctors about clients who may be at risk from doctor shopping, would undertake investigations and take action of both doctors and clients. There are 11 PHUs located around Qld who have EHOs who are appointed as Inspectors under the Health Act 1937 who have the ability to undertake these investigations*.

4.1.4 Enforcement

MRQ indicated that their monitoring and enforcement activity is based on a risk matrix (see appendix 6) that involves:

- examining non-compliance and determining the level of risk associated with non-compliance with the legislation
- identifying the enforcement options using a risk based enforcement tool to determine the most effective and consistent means of rectifying identified non-compliance
- commencing the decided enforcement action
- reviewing decisions as part of an on-going enforcement strategy.[50]

MRQ further advised that its enforcement activity involves a graduated approach including:

- educative and advisory actions to inform individuals of their legislative obligations
- issuing verbal or written advices or directions
- issuing non-compliance or improvement notices
- instituting legal proceedings
- administrative law action such as cancellation of an approval, licence or endorsement.[51]

From the information provided by MRQ, it was not clear to me how the risk matrix was applied in practice by MRQ staff in a consistent and transparent manner.

Based on the information provided to me by MRQ, the most common action taken by MRQ was of an advisory or educational nature. This involved providing written correspondence to health practitioners informing them of the issue identified through surveillance activities. Most frequently this relates to patients consulting multiple practitioners to access schedule 8 medicines. In 2014, MRQ staff sent more than 1000 letters to health practitioners in relation to potential schedule 8 medicines prescription

[50] MRQ submission
[51] MRQ submission

shopping by patients, despite there being no enforcement provisions in relation to high risk drug seeking behaviours.

The effectiveness of this as a risk mitigation strategy is unclear. During my investigation, HHSs raised concerns about the high number of letters sent to health professionals by MRQ regarding schedule 8 medicines prescription shopping by clients without timely follow-up action by MRQ. HHSs also commented that public health units are ideally placed to undertake this follow-up activity and conduct interviews with prescribers—a function that staff of public health units undertook prior to devolution.

In contrast, between 2010 and 2014, MRQ instigated on average only three to four investigations per year into the prescribing or dispensing behaviours of health practitioners. In addition, only nine prescribers had their endorsements cancelled in the same time period, with another eight voluntarily surrendering their endorsements.[52]

I am uncertain whether the small number of investigations undertaken by MRQ and/or the number of prescribers having endorsement cancelled or voluntarily surrendering their endorsement reflects the effectiveness of the advice/education risk mitigation strategy.

Given that MRQ has only one dedicated investigator within the current structure, it is not surprising that MRQ conducts on average three to four investigations per year into the prescribing or dispensing behaviours of health practitioners.

On the other hand, my office had more than 50 open investigations in the 2014–15 financial year that involved allegations that involved serious risk to the health and safety of the public in relation to schedule 8 medicines. Moreover, in its submission, AHPRA reported receiving more than 50 notifications due to concerns about inappropriate prescribing or dispensing of schedule 8 medicines in 2014. Therefore, I am concerned about the capacity of MRQ to interrogate the information in MODDS and identify at-risk practitioners.

I also note that there appears to be some evidence that MRQ focuses its investigative activities in South–East Queensland, as raised by a HHS during my investigation and supported by a job description for an MRQ investigator position that stated that some travel may be required to areas such as the Gold Coast, Metro North and Metro South HHS.

The various activities undertaken by MRQ are, to a large extent, underpinned by competing imperatives. As has been identified in reviews previously undertaken of the Drugs of Dependence Unit—MRQ's predecessor—the administrative, educative, therapeutic, and monitoring and enforcement responsibilities of MRQ do not necessarily sit easily side-by-side.[53]

My impression is that the focus of MRQ, in line with that of its predecessor, is on improving clinical outcomes through education and advice rather than monitoring, investigating and enforcing compliance with legislative requirements. While education and advice are worthy outcomes, it appears that a large

[52] MRQ submission
[53] MRQ Submission

part of the functions assigned to MRQ under the *Health Act 1937* and its subordinate legislation are not being fully and effectively performed.

In my view, it would be a more effective use of MRQ's current resources to focus on the monitoring of MODDS data and to develop and implement clear thresholds on how to escalate a matter appropriately, where initial advice and education provided is seen to be ineffective in achieving compliance. In developing consistent and appropriate escalation thresholds, MRQ should also disseminate information as widely as possible on how it intends to escalate matters and its reasons for doing so. I note that in response to the draft report I provided to agencies for their review and comment, the Director-General of the Department of Health advised that the Chief Medical Officer and Healthcare Regulation Branch is currently developing policies and procedures to support the effective separation of the investigations function from MRQ, and this includes escalation thresholds.

I further noted that there did not appear to be any clear guidance within MRQ on an escalation policy or a proactive information dissemination policy to other relevant regulatory agencies to deal with emerging issues adequately and in a timely manner. In my view, ensuring effective compliance with regulatory requirements related to schedule 8 medicines is a key element in safeguarding the health and safety of the public. Adequate compliance monitoring and enforcement activity requires a systematic and consistent approach to ensure that risks associated with non-compliance are identified and responded to in a timely manner. Monitoring must be accompanied by risk-based, proportionate enforcement action in instances of non-compliance to ensure effective regulatory implementation.

4.2 Public health units

HHSs employ environmental health officers (EHOs) as part of their PHU environmental health teams. EHOs are appointed by the Director-General of the Department of Health as inspectors under the *Health Act 1937.* At the time of this report, there were approximately 130 EHOs across the 11 PHUs. EHOs are trained in environmental health science, regulatory functions, risk assessment, investigation and enforcement.

It is evident that, similarly to MRQ, PHUs and EHOs undertake a number of different activities related to the *Health Act 1937* and associated regulations in general, and scheduled medicines and poisons in particular.

Activities undertaken by EHOs include:

- providing education and advice to health professionals on regulatory compliance requirements
- overseeing audits of the majority of *as-of-right*—i.e. implicit endorsement and approval holders
- investigating and responding to suspected non-compliance and complaints.

HHSs indicated that their regulatory intervention is guided by Department of Health enforcement guidelines which recognises the need for application of escalating enforcement responses. The options appear to be consistent with the graduated approach outlined by MRQ, and include:

- educative and advisory actions to inform individuals of their legislative obligations
- issuing verbal or written advices or directions
- issuing non-compliance or improvement notices
- referrals to relevant agencies or professional bodies
- instituting legal proceedings.

Once a PHU decides there is sufficient evidence for a prosecution, and it is the most suitable enforcement action, the PHU submits the brief of evidence to MRQ to seek their concurrence to proceed.

From the information provided to me by PHUs, it is not clear where PHUs direct most of their regulatory activity with regard to schedule 8 medicines. Evidence of the educative role of PHUs regarding compliance requirements was provided in AHPRA's submission which reported that a PHU had provided education sessions for pharmacists following the introduction in 2011 of section 84(10) of the Health (Drugs and Poisons) Regulation 1996. AHPRA went on to comment that further and continuing education for pharmacists to increase awareness of their responsibilities, and of MRQ's functions, is necessary to ensure compliance with these provisions.

Several HHSs informed me that EHOs in PHUs routinely undertake enforcement activity in response to regulatory non-compliance, including conducting investigations and prosecution of individuals and companies for alleged offences under the Health (Drugs and Poisons) Regulation 1996. For example, a major medicines wholesaler for not reporting suspected lost or misappropriated controlled drugs, a pharmacist who did not store and make appropriate records of controlled drugs and a pharmacist for poor dispensing practices. However, I was not provided with any specific data on the number of investigations or other types of regulatory action taken by any PHU. I note that one HHS indicated that PHUs were no longer likely to invest resources in complex investigations due to, what they perceived to be, a lack of support by MRQ for prosecution of these matters.

Under the Health (Drugs and Poisons) Regulation 1996, pharmacists have specific obligations to undertake stocktakes and report discrepancies to MRQ. In its submission, AHPRA noted that historically the Pharmacy Board of Queensland had monitored the approval of pharmacy premises for compliance with legislative requirements (specifically compliance with the ownership provisions), but that that function was specifically excluded from the National Law and transferred to MRQ. However, in its submission, MRQ stated that it:

> *…does not undertake compliance audits as part of its business … compliance and inspection audits are undertaken by the Public Health Units (PHUs) of the Hospital and Health Services (HHSs). The HHSs are independent statutory entities and provide regulatory support to the department*.

Based on the information provided to me, I am unable to determine if there is any routine inspection or audit schedule to monitor pharmacy compliance with legislative requirements around schedule 8 medicines. However, I note that MRQ indicated that:

> *…routine inspectorial activities are undertaken according to strategically planned work schedules based on public health priorities. Audits of particular facilities or health practitioners activities can be based on emerging issues or intelligence supporting concerns about non-compliance and/or public health risks*.

Under the Health (Drugs and Poisons) Regulation 1996, hospitals are required to notify MRQ of any discrepancy and of any lost or stolen schedule 8 medicines. While I am unable to determine the level of compliance with the requirement to report discrepancies, I note that the prescribing, storage, dispensing and disposal of schedule 8 medicines in hospitals are not subject to the same monitoring regimes as medical practitioners.

Further, HHSs reported the following matters arising from their involvement in managing schedule 8 medicines:

- Stock returns frequently rely on an honesty system and are not captured in the current auditing process. In situations where an honesty system is not in use, there are still concerns that returns are subject to diversion.
- The current design of prescription pads has the potential to create barriers to effective investigation of suspected misappropriation of medicines, including schedule 8 medicines, as the empty script book retains no record of the prescriptions filled, inhibiting an effective reconciliation process.
- Pharmacists are required to keep a schedule 8 medicines register but there is no requirement for pharmacists in community health service settings to check balances on a regular basis which allows discrepancies to go unnoticed for extended periods. In response to my draft report, the Director General of the Department of Health advised that it is proposed that the new legislation will require timely checks in pharmacies, not just when a pharmacist takes over for more than seven days.
- Sites where health professionals who are not pharmacists oversee supply could result in lower levels of compliance.
- There appears to be no requirement to report discrepancies in audits of schedule 4 and schedule 8 medicines to the QPS. A review of HHS policies and procedures indicates reporting is discretionary and is dependent on the volume involved and whether preliminary investigations can or cannot account for the missing medicines. In response to my draft report, the Director-General of the Department of Health advised that a system has now been established for the reporting of schedule 8 medicine discrepancies, although it was not explicit in the Director-General's response that this system involved the QPS.

4.3 Clarity around agency roles

It is clear to me that successful cross-agency collaboration requires a shared understanding of the roles, responsibilities and contributions of all stakeholders, in particular recognising the legislative responsibilities and priorities of individual agencies.

Blurred roles and responsibilities reduce the efficiency and effectiveness of service delivery, and obscure accountability, as well as create the opportunity for unrealistic expectations between agencies.

My investigation identified that a lack of clarity regarding the roles and responsibilities of the different parties involved in regulating schedule 8 medicines in Queensland is hindering effective regulatory action. In particular, effective working relationships between entities are being significantly degraded by the lack of an articulated position on the different operational priorities, cultures, risk profiles and skill sets of the agencies involved.

As mentioned previously, while MRQ has primary responsibility for administering the *Health Act 1937* and its subordinate legislation as it relates to schedule 8 medicines, my investigation was unable to identify any clear delineation of MRQ's current role and purpose.

In addition, my investigation did not identify any current document that clearly delineated the legal and policy roles and responsibilities of the other major stakeholders—such as my office, AHPRA and the QPS—as they apply to the regulation of schedule 8 medicines. I note that the *State-wide compliance plan 2015-16 and 2016-17* provided to me by MRQ identifies the responsibilities for MRQ and the PHUs.

Further, my investigation identified few formal documented cross-agency agreements held by MRQ that defined the roles and responsibilities of other stakeholders involved in regulating schedule 8 medicines, particularly in areas of shared responsibility such as enforcement and prosecution. Moreover, those documents that were identified were very broad and/or obsolete. For example, the *Public health manual*, which is intended to articulate the characteristics of instances where the Chief Health Officer and Prevention Division in the Department of Health (to which MRQ belongs) will *step in* to coordinate activities relating to an issue of significance that may have cross-boundary implications for HHSs, is currently under review

There are clearly key areas of intersection and overlap between the roles and responsibilities of MRQ and other agencies—such as my office, AHPRA, QPS and HHS public health units, in particular—in relation to:

- investigating concerns about compliance with expected standards of practice and/or legislative requirements related to schedule 8 medicines
- prosecuting unlawful behaviour related to schedule 8 medicines that fall within the category of dangerous drugs
- taking disciplinary or administrative action in relation to non-compliance with the requirements of the Health (Drugs and Poisons) Regulation 1996.

However, it became apparent during my investigation that MRQ operates what I consider to be a *silo* approach to regulation.

When reviewing the evidence for matter which have come to the attention of my office, some indicate that MRQ had been aware of serious concerns regarding the practitioner prescribing schedule 8 medicines for extended periods of time before advising my office (and AHPRA prior to the formation of the OHO) of the concerns. In one case, MRQ had been aware of prescribing concerns for at least 17 months before advising me and, in this particular case, when MRQ first identified concerns, its records showed a problematic pattern of prescribing had already been evident for at least three years.

Case study—Inappropriate prescribing of schedule 4 and schedule 8 medicines by medical practitioner to drug dependent patients

It is unlawful for medical practitioners to prescribe schedule 4 or schedule 8 medicines to a notified drug dependent person without prior approval from MRQ.

A medical practitioner breached these requirements on at least 273 occasions over a two year period.

MRQ took action in relation to the practitioner's non-compliance with his legislative requirements almost 18 months after the first instance of non-compliance. It took a further 12 months for the practitioner's authorisation to prescribe schedule 4 and schedule 8 medicines to be cancelled.

The Office of the Health Ombudsman was not notified of this practitioner's behaviour until MRQ had provided the practitioner with a notice to show cause as to why his endorsement should not be cancelled—more than two years after the initial non-compliance and a year after MRQ commenced action.

Based on the information gathered during my investigation, there is insufficient clarity regarding the role and responsibilities of MRQ or the other agencies with a role in the regulation of schedule 8 medicines. In addition, the lack of role clarity and guidelines around escalation and information sharing across the multiple agencies with responsibilities within this regulatory space is leading to sub-optimal outcomes in the management of the risk to the health and safety of the public from schedule 8 medicines.

This view was supported by HHSs, with one HHS stating:

> *…agree that there is a lack of clarity for HHS, with some overlap and duplication of roles. HHS would appreciate clarity about who to contact when concerns are raised about the misuse, and a single data entry/initial contact that meets the needs of all agencies should be considered. Simplifying the process with a flowchart would be appreciated.*

Another HHS stated:

> *…there is a need to clarify the roles and responsibilities of HHS PHUs and MRQ*.

A further HHS suggested that:

> *As PHUs are operationally focused and enforce the legislation, MRQ should be structured and focused on policy and strategic direction regarding the legislation and the PHUs have the enforcement focus. This model would reduce the regulatory responsibility confusion between agencies and the Department of Health…It is recommended that MRQ continue to provide clinical support and advice but enforcement be clearly the role of the operational units…*

A forth HHS noted that they have been of the view for some time that the therapeutic arm of MRQ should be separated from the enforcement arm, with the enforcement function extended to again include investigators in PHUs.

In my view, a thorough review of the roles and responsibilities of MRQ, in the context of the roles of other agencies with intersecting responsibilities, would provide an opportunity to clarify and focus governance in this area and produce efficiencies in service delivery to improve the protection of the health and safety of the public—a view shared by PHUs.

In my view, the involvement of other key stakeholder agencies in any review of MRQ's role and responsibilities is critical to identifying the most appropriate model for regulatory action and the allocation of scarce resources. Moreover, this will ensure all agencies are informed of and committed to any proposed changes to roles and responsibilities.

4.4 Undoing knot 2

I recommend that the Director-General of the Department of Health:

6. Establishes a committee to undertake a review of the roles and responsibilities of MRQ in light of the roles and responsibilities of the other agencies involved in regulating schedule 8 medicines. The review committee should include representatives from all key stakeholder groups including MRQ, my office, AHPRA, QPS, the Office of the State Coroner and Hospital and Health Service public health units. This review should consider
    a. whether MRQ maintain each of its administrative, educative, therapeutic, and monitoring and enforcement functions
    b. which agency within the regulatory environment is best equipped to take on the lead role in relation to each function
    c. the identification of shared performance indicators, reporting arrangements and outcomes, where possible
    d. the creation of appropriate governance arrangements to support decision-making and performance monitoring.

Subject to the outcome of the review, I recommend that the Director-General of the Department of Health:

7. Considers the development and documenting of a formal agreement setting out a clear statement of shared purpose and agreed roles and responsibilities of each of the agencies.
8. Ensures that MRQ, my office, AHPRA, QPS, the Office of the State Coroner, and Hospital and Health Service public health units communicates the agreed roles and responsibilities of each of their respective agencies clearly and regularly to all agency staff.
9. Reviews current resourcing levels and determines the resources required for MRQ to appropriately perform its functions.

10. Identifies *trigger points* for information sharing and referral between agencies in consultation with key agencies including MRQ, my office, AHPRA, QPS, the Office of the State Coroner and Hospital and Health Service public health units.

11. Directs MRQ to review its compliance and enforcement framework and to undertake a current risk assessment of work practices, including surveillance thresholds and criteria, at regular, prescribed intervals.

Responses to recommendations

In response to the draft report, the Director-General of the Department of Health proposed recommendation 6 be changed as he considered that if the other recommendations were addressed the recommendation was not necessary. This proposal was also proffered for recommendations 6a and 6b.

The Director-General indicated the Department of Health agreed with recommendation 6c, although was of the view that this should be part of recommendations 6d, which the Director-General considered should be a stand-alone recommendation—not an element of recommendation 6 overall.

One HHS commented in relation to recommendation 6 that they:

> *…recognise that in some instances adding a new committee adds complexity without always adding value. We feel that further definition (short vs long term) or potentially designating it as a Steering Committee or a Working group may result in a better collaboration.*

In response to recommendation 9, the Director-General indicated that the recommendation does not take into account the restructure of MRQ effective as of 25 July 2016. I accept that changes to MRQ have occurred since my investigation commenced and have made note of this in my report. However, based on the information provided, I am unable to determine to what extent consultation occurred with relevant stakeholders about the re-structure of MRQ, although I note that my office was not requested to provide any input into the changes that have been made. I am of the view that the need remains for an inclusive forum that supports collaborative action and provides oversight and accountability.

The Director-General indicated that the Department of Health would develop a response to recommendations 7, 8, 10 and 11 once the final report was available. I will review the Department's response when it is provided to me and, if warranted, may provide a supplementary report.

In response to recommendation 9, the Director-General also noted that an internal audit had recently been conducted on the administration of portfolio legislation within the Prevention Division of the Department of Health, in which MRQ is located. The Director-General noted further that, in addressing the audit's recommendations, the Prevention Division has developed a set of policies and procedures to improve its administration of legislation. This includes the requirement to regularly review work practices.

In response to recommendation 10, one HHS noted that:

> *…there are already such trigger points in use, e.g. the mandatory notification provisions in the National Law, the Queensland Police Service (QPS) triggers for informing Queensland Health (QH) of offences by using section 10.2 of its act, QH's reporting obligations to the QPS etc.*

While I note this, I am of the view that existing triggers do not adequately facilitate communication between all relevant agencies.

5. Knot 3—Policies and procedures

It was evident during my investigation that there is a lack of current overarching relevant state policy statements to support policy implementation. In my view, detailed over-arching policy statements provide guidance for the development and integration of agency responses, as well as ensure certainty on the part of agency officers charged with delivering these responses. In addition, documented policies and procedures also assist with ensuring objectives are achieved, managing risks and facilitating the use of resources responsibly and with accountability.

My investigation identified a lack of easily accessible, authoritative policies and procedures and supporting documentation to underpin and guide the work of the staff of MRQ.

While MRQ provided me with copies of numerous documents to demonstrate their monitoring and responding practices, it was clear during my investigation that there was an overall lack of current formal written policies, procedures, guidelines and work instructions, and that existing documents were not collated in one place.

For example, while MRQ supplied copies of procedures for responding to requests for information from external agencies such as the Office of the State Coroner, it did not provide a copy of any document that outlined the operational procedures for one of its officer undertaking an investigation of suspected non-compliance with Health (Drugs and Poisons) Regulation 1996 requirements.

In addition, existing documents supplied to me during my investigation did not always appear to be up-to-date and to reflect current organisational structures and processes. For example, the most recent version of the operations manual for MRQ's electronic alert system for monitoring prescription medicines was dated 2009 and referenced the former Drugs of Dependence Unit. While it is possible that the content of this document and others supplied is still relevant and applicable, in their current form they do not provide the necessary confidence that processes are current or consistent.

Having clear, up-to-date documents would support any monitoring and compliance activities undertaken by MRQ officers and would have a significant effect on the efficiency and transparency of these activities.

During my investigation, MRQ acknowledged that constant changes within the structure of the Department of Health have had an impact on the ability to respond to issues relating to prescribing and dispensing of schedule 8 medicines. The frequency of these changes are likely also to have contributed to delays in formalising changes to procedures and updating relevant documents.

In my opinion, the documents provided by MRQ do not provide evidence of adequate operational guidance to ensure a clear understanding by staff of the core purpose of MRQ, or establish well-defined standards of practice. I am of the view that the failure to develop and maintain, and make easily accessible to all MRQ staff, appropriate documentation presents a significant risk of inconsistent monitoring practices and decision making, as well as reduces transparency of the operations of the agency.

5.1 Undoing knot 3

I recommend that the Director-General of the Department of Health:

12. Directs MRQ to review its existing documentation and develop a consolidated and current authoritative version of all policies and procedures.

Responses to recommendations

In response to the draft report I provided to agencies for their review and comment, which included my proposed recommendations, the Director-General of the Department of Health indicated that the department would develop a response to recommendation 12 once the final report was available. I will review the department's response when it is provided to me and, if warranted, may provide a supplementary report.

6. Knot 4—Communication and collaboration

Building and maintaining effective and efficient partnerships is a core requirement of any complex regulatory framework. From the information I obtained and reviewed during my investigation, it is clear that the level and nature of contact and communication between the various regulatory agencies in this area differs, as would be expected, according to their different remits.

However, despite the differences, there is a clear lack of information sharing between agencies that deal with many interrelated matters each year.

For example, my investigation identified that between 2010 and 2014:

- MRQ only received 38 requests for information from the Office of the State Coroner[54]
- MRQ only provided information to QPS on 52 occasions, 24 of those occurring in 2014[55]
- AHPRA only requested information from MRQ on 12 and 26 occasions in 2013 and 2014 respectively.[56]

Additionally, despite the fact that MRQ sent out thousands of letters to health practitioners relating to concerns over schedule 8 medicine prescribing or dispensing behaviours, MRQ made very few referrals to AHPRA about this same matter (see table 3).

Table 3 Outgoing Medicines Regulation and Quality correspondence and notifications

Outgoing MRQ correspondence and notifications[57]	2012[58]	2013	2014
Correspondence from MRQ to health practitioners identified via routine surveillance alerts[59]	324	2084	3026
Notifications from MRQ to AHPRA due to concerns about inappropriate prescribing of schedule 8 medicines	16	8	6

In its response to my draft report, AHPRA acknowledged that, in view of MRQs resource limitations, MRQ had worked collaboratively with AHPRA and the national boards and provided schedule 8 prescribing information to assist with complaints and compliance matters.

In response to my draft report, the Director-General of the Department of Health advised me that it is routine practice for my office and AHPRA to be advised of any action taken against a health practitioner. This comment appears to conflict with the numbers in table 3 above in relation to AHPRA.

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[54] MRQ submission
[55] MRQ submission
[56] MRQ submission
[57] Notification is the term used by AHPRA to refer to a complaint about a health practitioner's professional conduct, performance or health.
[58] 2012 does not include a full 12 months due to transition from DDU to MRQ and new way of recording this type of information.
[59] Refer to table 2 Current MRQ schedule 8 surveillance alerts

Unfortunately, the QPS indicated that its data systems were unable to provide any information on the number of referrals received about inappropriate prescribing or dispensing of schedule 8 medicines from agencies such as MRQ or AHPRA.

As previously referred to, I note from the investigations that my office conducts that there is often significant crossover between the regulatory activities of the OHO, AHPRA, MRQ, QPS and the Office of the State Coroner. Frequently, all stakeholders are involved in some form of investigation or regulatory response in relation to the same matter, with relevant information held by each agency. However, I have found that there can be a lack of agreement among the various agencies on communication pathways and processes for sharing information and documents, both formally and informally, when working towards achieving shared outcomes.

One HHS noted that:

> *…MRQ has restricted the activity of PHU EHOs in the medicines work area by:*
>
> - *…failing to share information when requested, which would allow PHU EHOs to quickly act on complaints. This includes not providing print-outs from MODDS and ceasing to forward hard copies of approvals/licences/permits issued by MRW. Often this information is not entered into MAPLE (a statewide licencing database) or is incomplete…*
> - *requiring all applications for licences, approvals and scheduled medicine discrepancy reports be forwarded to MRQ for initial processing and redistribution resulting in delays in processing…*

The example referred to in section 4.3, regarding MRQ's awareness of concerns with a practitioner's prescribing of schedule 8 medicines, illustrates just one example of many where the lack of timely referral or sharing of information with me has resulted in a significant delay in my office becoming aware of significant issues with a practitioner. This results in delays in the assessment of the risk the practitioner poses—particularly where non-compliance and/or risk has escalated over time—and delays in the implementation of appropriate risk mitigation strategies to protect public health and safety. In this example, MRQ was aware of the problematic and longstanding pattern of prescribing by the practitioner for 17 months, during which period there was no sharing of information with the agency (my office) established to deal with serious risk to the health and safety of the public.

HHS's were supportive of the timely exchange of information about suspected misuse of medicines between agencies with one HHS stating:

> *…[HHS] fully supports that any suspected misuse of medicines is reported to AHPRA and it should occur as early as possible in an investigations when concerns have been raised.*

During my investigation, a number of PHUs raised concerns about the lack of PHU access to the MODDS system. The PHUs commented that this not only restricts the ability of EHOs to undertake investigations, but that MODDS access would also complement pharmacy audits such that patients dispensed controlled drugs over a period of time could be identified and checked on MODDS as to whether further follow up is required. PHUs noted that EHOs in PHUs have access to other statewide databases including notifiable conditions and MAPLE.

6.1 Privacy concerns

The handling of personal information is regulated by privacy legislation at the federal and state levels. This legislation imposes limits on the manner in which government agencies use and disclose personal information they have in their position or control, including disclosure to other agencies.

One HHS stated:

> *…the need to ensure privacy is a barrier to clear communication and information in sharing in a timely fashion. It should be clearly articulated what information can be disseminated/shared at each point in an investigation…*

Another HHS noted:

> *…[PHU] work has been restricted when MRQ ceased access to MODDs (Monitoring of Dangerous Drugs) for PHUs due to privacy matters. This lack of access has hampered investigations at the PHU level…PHUs access other statewide DoH [Department of Health] databases… that can have client sensitive information.*

My investigation found that agency interpretations of the legislative requirements surrounding disclosure of personal information present a significant barrier to information sharing between agencies.

MRQ indicated to me it does not routinely receive notifications from AHPRA regarding concerns about inappropriate prescribing or dispensing of schedule 8 medicines or concerns around practitioner substance abuse or dependence. In MRQ's view, this was primarily due to legislative privacy and confidentiality provisions.

In determining when to share information it holds with other agencies, MRQ indicated it relies on legal advice which suggests National Privacy Principle 2(1)(g) of the *Information Privacy Act 2009* permits a health agency to disclose personal information where it believes the disclosure is reasonably necessary for one or more of the reasons identified under National Privacy Principle 2(1)(h) by or on behalf of an enforcement body. Additionally, that National Privacy Principle 2(1)(f) provides a mechanism for the disclosure of personal information by a health agency in circumstances where the health agency has reason to suspect unlawful activity is or may be engaged in, and the health agency discloses the personal information as a necessary part of its investigations or in reporting its concerns to relevant persons or authorities.

MRQ further states that, 'the established MRQ protocol is based on consideration of the onerous nature of privacy and confidentiality provisions as detailed above'.[60] This consideration would appear to have resulted in potentially unnecessarily formal processes for information sharing in some circumstances. For example, the established protocol between MRQ and QPS requires QPS to contact MRQ to request information from MRQ via a warrant for the information[61] and serve it with a written request for provision of a witness statement from the MRQ officer providing the information, along with a completed evidence

[60] MRQ submission
[61] Under the provisions of the *Police Powers and Responsibilities Act 2000*

certificate.[62] The current protocol between MRQ and the Office of the State Coroner is for a Coroner to issue a *Form 25 information requirement notice*.[63]

6.2 Non-legislative barriers

Barriers to information sharing are not, however, always legislative in nature. Often the obstacles are cultural, or arise from an excess of caution based on a lack of understanding of the relevant rules.

AHPRA indicated to me that it is of the view that the existing information sharing provisions, 'could be interpreted more broadly to ensure that concerns about registered health practitioners (for [AHPRA's] context) are raised with the relevant regulators as soon as possible'.[64]

I note that section 10.2 of the *Police Service Administration Act 1990* provides a mechanism for QPS officers to provide intelligence or information to external agencies where that information is relevant to the business of that agency. Prior to 26 June 2015, section 1.9.21 of the QPS Operational Procedures Manual provided discretionary and mandatory requirements for QPS officers to provide information to AHPRA regarding the conduct of health practitioners. The QPS used this provision on a number of occasions to provide information to AHPRA, which I note has in the past resulted in action being taken against health professionals by the relevant national board.[65] I also note that from 26 June 2015, the mechanism to enable provision of this information to AHPRA and the national boards is addressed by section 5.6.21 of the QPS Management Support Manual.

6.3 Formal mechanisms for information sharing

My investigation identified a lack of formal mechanisms for communication, coordination and collaboration around the sharing of relevant information between agencies. My investigation also identified a need for the development and implementation of governance structures and mechanisms to support timely, effective and consistent information sharing and collaboration.

A memorandum of understanding outlining the coordination of responses to serious adverse health incidents previously existed between the former Health Quality and Complaints Commission, AHPRA, the Office of Health Practitioner Registration Boards, Office of the State Coroner, the former Crime and Misconduct Commission, QPS, Queensland Ombudsman, and the former Commission for Children and Young People and Child Guardian. Since the changes to, or dissolution of, many of these agencies, this agreement has become irrelevant.

A memorandum of understanding for the exchange of information between Queensland Health and QPS was also previously endorsed by the Chief Health Officer and Commissioner of the QPS. However, I was advised by the QPS that since the restructure of Queensland Health in 2013, the memorandum of understanding has been argued as not relevant to the HHS operating environment and, as such, has

[62] Pursuant to section 95, Evidence Act 1977.
[63] Pursuant to section 16(2) *Coroner's Act 2003*
[64] AHPRA Submission
[65] QPS Submission

become ineffective.[66] MRQ expressed the view that, in the absence of an information sharing memorandum of understanding with the QPS, MRQ does not have the ability to make referrals to QPS.

AHPRA indicated to me that it is in the process of renegotiating memorandums of understanding with both QPS and the Office of the State Coroner.

Agencies have told me that formal information-sharing processes were necessary, and have demonstrated a willingness to engage further with this issue. It may be that formal timeframes and a requirement for coordination of this process is all that is needed to ensure the best outcomes across the regulatory framework.

In addition to formal information sharing agreements, it is my view that regular formal liaison meetings should occur between key stakeholders to share relevant information on each agency's activities, and to enable focus on individual matters or emerging trends affecting the various agencies.

I accept that, with collaboration between agencies of this nature, there is no single perfect structure or process. Achieving improved and broader collaboration and information sharing will require both better use of existing structures and processes within the existing regulatory framework, as well as the development of new methods of sharing information.

QPS has suggested a revised memorandum of understanding enabling the sharing of information between the QPS and MRQ and HHSs should be considered, and that the establishment of a coordinated group—including representatives from Office of the State Coroner, QPS, Department of Health and my office—could enhance the joint agency response to these issues. I strongly support both of these suggestions.

In contrast, one HHS indicated that it saw no need for a memorandum of understanding stating that:

> *…provided it is clear how privacy concerns are handled, [sharing of information] should happen automatically if the legislation supports it.*

6.4 Undoing knot 4

I recommend that the Director-General of the Department of Health:

13. Coordinates a consultation process to develop formal written multi-agency agreements that outline mechanisms for the exchange of information about schedule 8 medicine matters, and that these agreements include are requirement for regular review.
14. Coordinates regular formal liaison meetings between key stakeholders including my office, AHPRA, MRQ, the QPS and the Office of the State Coroner (at least every two months initially).
15. Explores changes to legislation to improve the ability of agencies involved in schedule 8 medicine management to share relevant and confidential information to improve the timeliness of risk mitigation strategies to ensure health and safety of the public.

[66] QPS Submission

Responses to recommendations

In response to the draft report I provided to agencies for their review and comment, which included my proposed recommendations, the Director-General of the Department of Health indicated that the department would develop a response to recommendations 13, 14 and 15 once the final report was available. I will review the department's responses when they are provided to me and, if warranted, may provide a supplementary report.

7. Knot 5—Real time prescription monitoring

Given the increased number of schedule 8 medicine prescriptions dispensed in Australia, including opioids and benzodiazepines, and the related increases in the harm associated with misuse of these medicines, there has been considerable interest in innovative strategies that either minimise these harms or enhance the potential monitoring and enforcement options.

The implementation of real time prescription monitoring (RTPM) has been of particular interest to policy makers and regulators over the years. RTPM systems electronically collect information about the prescriber, the dispenser, the patient and relevant drugs at the time of dispensing.

The National Pharmaceutical Drug Misuse Framework for Action 2012–15 identified as the first of its nine national priority areas the introduction and implementation of an online, real time medication management tool that would provide access to information on patients' medication usage to prescribers, dispensers, and regulators. The framework argued that a RTPM system could identify the following:

- irregularities in treatment, such as excessive prescription amounts and early repeat dispensing
- drug seeking by individuals attending multiple prescribers and pharmacies, hospitals, specialists and other settings
- whether purportedly lost prescriptions have been filled
- patterns of dispensing which are suggestive of fraudulent activities undertaken to obtain medicines (such as forgery and alteration of prescriptions) and flag problematic prescribing or dispensing patterns
- where criminal activity is indicated, provision to share this information could be directed to the relevant agencies such as law enforcement.

In July 2010, the Australian Government announced the rollout of a real time drug monitoring initiative, the Electronic Recording and Reporting of Controlled Drugs (ERRCD) system. This was part of the Fifth Community Pharmacy Agreement, an agreement between the Australian Government and Pharmacy Guild of Australia to assist in providing ongoing medication management services to community pharmacies across Australia.

Currently, Tasmania is the only state to have adopted the ERRCD system, although I am aware that the Australian Capital Territory has implemented a form of real time reporting for controlled medicines.[67] In April 2016, the Victorian Government committed to the introduction of a RTPM system. My understanding is that other state and territory medicine regulatory bodies continue to engage and discuss their progress towards a similar system.

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[67] ACT Government Health, N.D., Sparrow, M 2006, *Implementation of a real time reporting system for controlled medicines in the ACT*, viewed 8 June 2016, ACT Government <http://www.health.act.gov.au/sites/default/files/Implementation%20of%20a%20real%20time%20reporting%20system%20for%20controlled%20medicines%20in%20the%20ACT%20Information%20Sheet.pdf>

7.1 The need for a real time prescription monitoring system

MRQ currently collects and monitors information about the prescriber, dispenser, patient and schedule 8 medicine through the MODDS.

The information obtained during my investigation, including documentation provided by MRQ, relevant stakeholder submissions and other research I have undertaken, indicates that MODDS is not presently an effective support for either practitioners' clinical decision making, or the actions of regulatory bodies such as MRQ.

Dispensing data of schedule 8 medicines is not provided in real time. Therefore, MRQ is unable to respond immediately to issues or concerns that arise and, particularly, to provide up-to-date information to practitioners. The inability for prescribers and dispensers to be alerted to potential misuse of schedule 8 medicines in real time means preventative action may be unavailable or delayed, with less of an impact or worse, with increased risk to health and safety.

MODDS currently relies on the prescriber/dispenser to form a suspicion prompting a request for information from MRQ about an individual. Prescribing information is not routinely checked for all patients, or even for high-risk patient groups or high-risk prescribing.

A key limitation of MODDS is that access to the system and the significant data stored there is restricted to MRQ. Prescribers and dispensers do not have access to this system, so are not able to see what prescriptions a consumer is using. Further, MRQ is not required to share or report information that may be of significance to another agency. The difficulties faced by law enforcement during their investigations has been noted in a number of documents including the National Pharmaceutical Drug Misuse Framework for Action 2012–15.

Specifically, QPS advised that there is no opportunity to obtain information from MRQ via alerts received through MODDS, which would otherwise assist in their investigations of drug-related offences. At present, QPS are required to present a warrant to obtain information from MRQ. In its submission, QPS advised it was often called to chemists and pharmacies in relation to the presentation of a prescription suspected of being fraudulent. There is limited ability for QPS officers to obtain timely information to determine whether scripts from the same doctor or prescribed to the same person have been presented and at which locations (which would provide information as to whether there is a single offence, or a number of offences to investigate). Often, because the information is not available in a timely manner, the offender is able to commit multiple offences before QPS can establish sufficient evidence for an arrest and may place themselves or the public at significant risk of harm if the offence relates to the misuse of schedule 8 medicines.

During my investigation, it was clear that most stakeholders considered that the most favourable solution to enable effective monitoring of schedule 8 medicines is to implement a RTPM system. Some of the submission comments are noted below.

Support for a real time prescription monitoring system

AHPRA—*Any system that raises relevant alerts in real time would be advantageous. It is AHPRA's experience in Queensland that by the time concerns are raised about an individual's use of, prescribing of or dispensing of schedule 8 medicines, there could have been a lengthy period of abuse or of inappropriate prescribing or dispensing.*

Pharmacy Guild of Australia—*There is a need for real-time monitoring/reporting...*

QPS—*It is recognised that a national system such as the Electronic Recording and Reporting of Controlled Drugs (ERRCD) would assist prescribers and pharmacists in the management of patients with a therapeutic need for controlled drugs while informing prescribers about potential 'at risk' patients and suspicious behaviour.*

Hospital and Health Service—*A national database of all schedule 8 prescribing and dispensing including non-PBS & public hospital dispensing that integrates with medical officer prescribing software and pharmacist dispensing software at the point of care, must be mandatory for all prescribing and dispensing health practitioners and consumers.*

Hospital and Health Service—*we fully support … a real time prescription monitoring system for schedule 8 medicines and note that to be truly useful, it must capture data Australia-wide, rather than by state.*

Unfortunately, the misuse and abuse of schedule 8 medicines and the challenges faced by practitioners involved in the management of complex patients who require these medicines is evident in the increasing number of coronial investigations and inquests. The implementation of RPTM continues to be echoed among coroners in Queensland, Victoria and New South Wales dealing with the growing number of these cases and they share the frustration that the tool has still not been implemented Australia-wide. Such a system has been recommended at least 12 times since 2012.[68]

A RTPM would alert the prescriber and/or dispenser in real time to issues of misuse, oversupply, or prescription shopping and would allow them to engage with MRQ or other services available such as Prescription Shopping Programme and obtain appropriate advice and/or report potential misuse and initiate a plan of action.

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[68] Finding without Inquest into the Death of Glen David Kingsun, 28 July 2014, Victorian Coroner Heffey; Finding without Inquest into the Death of Simon Millington, 30 July 2014, Victoria Deputy Coroner West;Inquest into the Death of Anne Christine Brain, 12 October 2014, Victorian Coroner Judge Gray; Inquest into the Deaths of Christopher Salib, Nathan Attard and Shamsad Akhtar, 27 June 2014, New South Wales Deputy State Coroner C Forbes; Inquest into the Death of James 15 February 2012, Victorian Coroner Olle; Finding without Inquest into the Death of Rory Brett Denman, 8 March 2012, Victorian Deputy State Coroner
West; Inquest into the Death of David Andrew Trengrove, 18 May 2012, Victorian Coroner Jamieson; Inquest into the Death of Georgia Susan Cheal, 15 May 2014, Victorian Coroner Hawkins; Finding without Inquest into the Death of Kirk Ardern, 7 April 2014, Victorian Coroner Jamieson; Inquest into the Death of Paul Kanis, 17 December 2014, Victorian Coroner Heffey; Inquest into the Death of Bradley John Muller, 9 June 2010,Queensland Coroner Ryan; Investigation into the Death of Rachel Danielle Smith, 26 November 2014, Queensland Coroner McDougall; Inquest into the Death of Katie Lee Howman, 27 July 2015, Queensland Coroner Clemerts;

Case study

Most recently in July 2015, a, young mother of two who worked as a registered nurse died following an overdose of the drug fentanyl. The Queensland coronial investigation revealed the nurse was required to comply with mandatory drug testing directed by AHPRA for a previous overdose attempt while at work, and was attending numerous doctors and sourcing strong pain medication from multiple pharmacies. The coroner commented, *'there have been repeated previous recommendations made by coroners to improve the real time accessibility of information for doctors and pharmacists about their patient's history'*. The coroner goes on to make the recommendation, *'there be a statutory change to enable real time access to relevant prescription and doctor attendance history'*.

In addition, another Queensland coroner asked me to consider the following as part of his findings in the death of another young woman who was considered to be a *prescription shopper*:

> *There should be instituted a national computerised pharmacy system which automatically registers a patient's prescriptions as soon as it is dispensed which would alleviate the six week time gap from dispensing until the PSP send out notifications.*

Similarly, in December 2014, a Victorian coroner delivered findings into the death of a 38-year-old man with a long history of mental illness. The man died of pneumonia in the setting of methadone and benzodiazepine use. The coroner found that the deceased received care and prescriptions from two GPs who had never met or spoken to each other about him.

The above case study demonstrates the difficulties and challenges of not being able to share prescribing information between doctors and practices, and monitoring real time information from the point of prescriber or dispenser to prevent harm to the user.

Coronial inquest findings

The findings of Victorian Coroner Judge Ian Gray in a coronial inquest into the death of Ms Anne Christine Brain on 30 October 2014 demonstrated the advantages of a real time system, specifically noting Tasmania's DORA (Drugs and Poisons Information System—Online Remote Access), and how involved implementing a real time system would be. I have highlighted these specific findings:

- *A real time system would have enabled a complete understanding of Ms Brain's presentation and drug seeking, and therefore would have enabled the health practitioners to make more informed decisions about her health care.*
- *Real time prescription monitoring is an essential tool medical practitioners need for clinical management of their patients. Victorian coroners have called for the system through their recommendations in at least 12 findings.*

- *Mr Matthew McCrone, Victorian Department of Health Chief Officer for Drugs and Poisons Regulation provided evidence about Tasmania's DORA (Drugs and Poisons Information System—Online Remote Access), the platform used as part of the Fifth Agreement initiative, as well as Victoria's progress towards a real time reporting system. He provided the following information*
  - *The DORA system works through capturing information on schedule 8 drugs dispensed in Tasmanian pharmacies, and transmitting it at the time of dispensing to a central storage location where others can view it.*
  - *Although the DORA system is rolled out to 100% of pharmacists and is capturing all schedule 8 drug dispensing information, enabling access to this information is an ongoing process. In 2014, less than half of Tasmania's GPs had direct access to the DORA data when treating patients, and the rest needed to call the Tasmanian Department of Health and Human Services during business hours to make inquiries.*
  - *Implementing a real time system is far more involved than just putting the software, ERRCD, in place. The Department of Health released a tender document for a service provider to develop a business case to implement a real time system in Victoria. The business case examined both the real time system itself, and the way the system was to interface with the department's internal Drugs and Poisons Information System (DAPSIS). Three options were considered including development of an entirely new system and integration of the ERRCD into the existing DAPSIS. The business case was finalised in January 2014 and recommended one of the proposed options.*
  - *The remaining process includes an implementation study, case development including budgeting costs for funding through the budget process.*
  - *Privacy issues have been raised however in Victoria the real time system could be effected though subordinate legislation and not an Act of Parliament.*
  - *A range of costs that would be incurred include implementing the software, teaching prescribers and dispensers how to use it, maintaining the underlying IT infrastructure, leasing or purchasing the computer servers that store the data, maintaining software, sharing data and information between states, dealing with schedule 8 applications, monitoring prescriber compliance with permit conditions, and acting upon the hugely increased amount of drug dispensing information suddenly available to the department. (What the Commonwealth has offered (ERRCD) in regards to the cost of a real time system is limited in comparison to what the individual states and territories would need to fund.)*
  - *The expense incurred by Victoria would be far more significant than Tasmania based on the current population.*
  - *It is critical a national standard for data collection on drug dispensing events is used so the information shared is the same across the country.*
  - *Implementation of an RTPM system in Victoria would save lives and 'everyone' supports the need for RTPM.*
  - *Current legislation allows for a real time reporting system to monitor schedule 8 drugs.*

I have also noted the Royal Australasian College of Physicians and the Royal Australian College of General practitioners both recommended the adoption of a real time reporting system to operate nationally, and this is also supported by the Australian Government in its ERRCD initiative.

7.1.1 Other similar real time monitoring systems

A small number of other jurisdictions have implemented real time monitoring systems.

Tasmania's RTPM for monitoring schedule 8 medicines prescribed alone or in combination with alprazolam was the ERRCD's introductory platform. The Drugs and Poisons Information System—Online Remote Access (DORA) system is operational, but the objective was not carried out in any other state or territory. The impact of Tasmania's DORA system has so far been positive due to the availability of information to assist prescribers and dispensers in making better clinical decisions.

In the United States of America, prescription drug monitoring programs (PDMPs), similar to that of RTPM system, have been operating in each state and implemented as a direct result of national concern over illicit use and abuse of prescription drugs. PDMPs are used as a patient care tool, drug epidemic early warning system, and drug diversion and insurance fraud tool. It helps prescribers to avoid drug interactions and identify drug seeking behaviours or *prescription shopping*. In some states, professional licensing boards also have access to the PDMPs to identify clinicians with patterns of inappropriate prescribing and dispensing, and law enforcement in cases of diversion. PDMPs have been assessed to be effective at reducing the time required for drug diversion investigations, changing prescribing behaviour, reducing prescription shopping, and reducing prescription drug abuse.[69] Unintended consequences of this regulatory approach, such as shifts in prescribing patterns, have also been noted.

Another initiative I have come across during my investigation that demonstrates an effective real time monitoring system is Queensland's Project STOP that commenced in 2005. Project STOP is a web-based tool developed by the Queensland Branch of the Pharmacy Guild of Australia in consultation with the QPS and Department of Health to track pseudoephedrine sales in real time. The data collected can be monitored by law enforcement agencies and health regulators looking for inappropriate patterns of use. The success of the system saw it rolled out nationally due to a funding agreement with the Australian Government Attorney-General's Department in 2007.

These similar systems add to my confidence that a RTPM is feasible in Queensland.

7.1.2 Working towards a real time prescription monitoring system in Queensland

In light of the ERRCD, MRQ considered a review of their business processes and MODDS to determine whether any changes were required and how it might be achieved. Several documents provided by MRQ to my investigation indicate that further analysis was recommended of MRQ's business requirements and MODDS, as well as analysis of the gaps between the business requirements and ERRCD, to make an informed business decision about the real time monitoring of schedule 8 medicines. However, it appears that no cost analysis was included and as a result the assessment was considered incomplete.

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[69] Finklea, K., Sacco, L. & Bagalman, E. (2014). Prescription Drug Monitoring Programs. Congressional Research Service Report. 7-5700.

It is my understanding that MRQ has proposed modifications to the current MODDS to incorporate real time information rather than adopting the ERRCD. I was unable to find any further evidence in the documentation MRQ had provided that this had progressed or would progress.

Currently, I am unaware of any Department of Health budget allocation for the implementation of the ERRCD—neither have the potential costs been analysed in order to develop a business case for approval. My investigation found that other state and territory medicines regulatory units meet regularly and keep each other informed of their progress, as most are engaged in similar business assessments on whether to implement the ERRCD or another RTPM system. I endorse this engagement and am of the view that continued engagement and collaboration will support the selection of an RTPM model that will have taken into account the legislative and regulatory impacts, as well as factors like cross-border usage and the monitoring of trends across jurisdictions.

The technical solution to deliver a RTPM does not appear to be the challenge. During my investigation, I became aware of software alternatives, in addition to the existing ERRCD, currently available from private sector companies that specialise in health information technology and script exchange software. The available information indicates that software can be modified so it has the capacity to perform real time monitoring. As an example, MediSecure provided evidence in a recent Victorian coronial matter where they described their product DrShop—a prescription monitoring system developed to deter prescription shopping. MediSecure advised that it had limited real time capacity but modifications could be made to allow real time capture.

7.1.3 Considerations and capabilities

Delivering a RTPM system would mean access to a powerful tool to ensure real time monitoring of schedule 8 medicines to improve quality use of medicines and to assist prescribers, dispensers, and hospitals to make appropriate clinical decisions in relation to patient care. However, in developing such a system, a range of factors should be considered and potential capabilities carefully explored.

Collaboration

In all the documentation I have reviewed about RTPM, it is essential there is collaboration between government bodies, professional health groups, and consumer groups to guarantee a balance of protecting an individual's privacy, maximising patient safety and reducing the risk of medication misuse.

Workforce development

Workforce development for prescribers and dispensers will play a key role in the success of any RTPM system. Early engagement with professional clinical and pharmacy groups and other key stakeholders may identify opportunities for better infrastructure and skills to support the prescribers and dispensers communicating to patients about addiction and mental health.

Support and training for primary clinicians will be a key factor in ensuring an RTPM system is successful. It is worth noting that implementation of RTPM could be used to increase doctors' awareness of state-based regulation by providing prompts and links to the relevant regulations and guidelines.

Broader regulatory scope

Another possible extension and therefore an additional benefit to a RTPM could be the inclusion of data on the prescribing and dispensing of schedule 4 medicines. Currently, MODDS only collects and analyses data related to schedule 8 medicines. I do acknowledge that MRQ has also noted it would be of benefit to include schedule 4, and perhaps other non-controlled medicines. Australian coronial matters have shown that often a combination of schedule 8 and schedule 4 medicines contribute to morbidity and mortality rates, and for differing reasons. For example, a Victorian Coroner who investigated the death of a man in July 2014 commented:

> *Some patients, engaged in the practice described as "prescription shopping", will have a vested interest in concealing their full prescription history. Others, such as the deceased, with a complex and frequently changing medication regimen, are at risk of making unintended errors and omissions in their disclosure, particularly with respect to dosage or brand name.*[70]

I think it is also important to note that, by including the dispensing information for medicines other than schedule 8 medicines, we may avoid situations like that of the PDMPs in the United States where it has become evident that there is a shift of prescribing patterns towards less closely monitored medicines without substantially reducing harms, or the level of prescribing of monitored medicines.[71]

Data capture

An opportunity also exists to capture prescribing information relevant to the Pharmaceutical Benefits Scheme, Repatriation Pharmaceutical Benefits Scheme and private prescriptions, data which is not currently captured in MODDS. The inclusion of this data would provide a complete picture of prescriber and client usage when reporting and identifying trends. However, I note that the regulatory functions and resourcing of MRQ and/or other relevant agencies may need to be enhanced in order to respond to the additional information.

Obviously, careful consideration should be given to the relevant legislation to facilitate the sharing of information via a RTPM system, with issues of privacy of particular significance. Any system would also be required to stand up to audit activities and security scrutiny. Restrictions and provisions for those who require access to this system must be clear. For example, prescribers and dispensers should only have access to the information relative to the consumer under their direct care, and only to inform clinical management and treatment decisions.

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[70] Coronial findings into the death of Glen Kingsun

[71] Finklea, K., Sacco, L. & Bagalman, E. (2014). Prescription Drug Monitoring Programs. Congressional Research Service Report. 7-5700.

Resourcing and capacity

Further, the editorial in the September 2014 edition of the Drug and Alcohol Review, *Implementing real-time prescription drug monitoring: Are we ready?* noted that the overall impact of other health services needs to be considered, including services that provide drug treatment. It stated:

> *Referral pathways to specialist services need to be considered and established while ensuring primary, secondary, and tertiary services have the capacity to respond to the potentially large number of patients that may be identified…'*

Thought also needs to be given to those community and specialist drug treatment services often operating to capacity or which have substantial waiting lists, and rural and regional locations.[72]

Pain management trends

In order to appropriately manage consumer data, specific attention will need to be paid to the management of chronic pain. Chronic pain is a considerable health issue and often results in high use of opioids. Consumers who often fit in this category also often have complicated medical profiles and may be managed under a multidisciplinary medical team. The system needs to prevent stigmatisation and be capable of identifying the difference between patients who may be prescription shopping and patients being treated for long-term chronic and complex conditions under the management of multiple practitioners.

Improved prescribing

Finally, a RTPM system would also highlight concerns regarding the prescribing practices of practitioners. AHPRA noted in its submission to my investigation that detecting problematic prescribing was often difficult and that by the time concerns were raised about an individual's use, prescribing or dispensing of schedule 8 medicines, there could have been a lengthy period of abuse or of inappropriate prescribing or dispensing.

7.1.4 Summary

I am of the view that a RTPM system is a tool that would have significant benefits for the effective and efficient monitoring of the prescribing and dispensing of schedule 8 medicines in Queensland, as well as schedule 4 medicines if possible. A RTPM would also help to manage risks to the health and safety of the public created by the inappropriate prescribing or unlawful dispensing of such medicines.

In order to achieve the best possible outcome for Queensland, consultation should occur with key agencies and stakeholders such as MRQ, my office, AHPRA and the national boards, law enforcement agencies, the Pharmacy Guild of Australia, the AMA and with consumer groups.

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[72] Nielsen, S. & Bruno, R. (2014). Implementing real-time prescription drug monitoring: Are we ready? Drug and Alcohol Review, 33, 463-465.

It seems clear that the move towards a RTPM to date has been at various times affected by a variety of issues and changing priorities. Nevertheless, technically the system itself is within reach. Complexities include possible significant impacts on legislation, resourcing, health service delivery, workforce development and education, and the interactions and effects on stakeholders. All of these will require further thought and exploration.

It is evident to me that a real-time monitoring system is both feasible and essential to assist in the effective and efficient management of the prescribing and dispensing of schedule 8 medicines in Queensland and Australia.

7.2 Undoing knot 5

I recommend that the Director-General of the Department of Health:

16. Directs an expeditious review of Queensland Health's options for the introduction of a RTPM system in Queensland and the subsequent development of a business plan to progress the implementation of a RTPM system.

Responses to recommendations

In response to the draft report I provided to agencies for their review and comment, which included my proposed recommendations, the Director-General of the Department of Health indicated that the department would develop a response to recommendation 16 once the final report was available. I will review the department's response when it is provided to me and, if warranted, may provide a supplementary report.

8. Conclusions

I am of the view that the current Queensland regulatory system for scheduled medicines as it applies to health services, in particular the prescribing and dispensing of schedule 8 medicines, contains a number of weaknesses. While these weaknesses continue to exist, there is an unacceptable risk that schedule 8 medicines could be subject to unauthorised access and misuse, which presents an ongoing risk to public health and safety.

Controls over the access to and the use of schedule 8 medicines do not consist solely of the formal law, regulations and offences, but are intertwined with complex social and clinical practice issues. This complexity, combined with the multiple agencies with overlapping policy and regulatory functions and responsibilities, necessitates substantial interagency collaboration and communication. It is clear from my investigation that this is an area which requires considerable development within Queensland.

In addition, the regulatory system must have the capacity to source and analyse data in a timely manner in order to effectively respond to emerging issues and manage risks to public health and safety. While the data currently collected by MRQ is undoubtedly valuable, there are substantial limitations. I am of the view, as are many others, that the introduction of a real time prescription monitoring system in Queensland should be progressed as a matter of urgency.

8.1 Full list of recommendations

Knot	Recommendations
1. **Legislative complexity**	I recommend that the Director-General of the Department of Health: 1. Continues to actively consult with stakeholders on the proposed new framework for the regulation of medicines, poisons and therapeutic goods in Queensland, in particular in relation to the prescribing and dispensing of schedule 8 medicines. 2. Takes into account the issues identified in this report in his consideration of the proposed new legislation. 3. Following the introduction of the new Medicines, Poisons and Therapeutic Goods Act, ensures that Queensland Health works closely with stakeholders—including national health practitioner boards, QPS, professional associations and organisations such as the Private Hospitals Association of Queensland—to implement a tailored education program aimed at each stakeholder group to ensure all are aware of their obligations under the new legislation. 4. Ensures MRQ continues and strengthens its work with the QPS to ensure adequate guidance is provided to QPS officers about the misuse of scheduled medicines and the availability of various charges, as well as the practical consequences of bringing charges under a particular Act. 5. Considers recommending to the Queensland Minister for Health to propose at the next Australian Health Ministers' Conference that amendments are made to the National Law to require practitioners disclose to their national board if the practitioner has been charged or convicted of an offence under drugs and poison legislation, whether in a participating jurisdiction or elsewhere.

2. **Roles and responsibilities**	I recommend that the Director-General of the Department of Health: 6. Establishes a committee to undertake a review of the roles and responsibilities of MRQ in light of the roles and responsibilities of the other agencies involved in regulating schedule 8 medicines. The review committee should include representatives from all key stakeholder groups including MRQ, my office, AHPRA, QPS, the Office of the State Coroner and Hospital and Health Service public health units. This review should consider: a. whether MRQ maintain each of its administrative, educative, therapeutic, and monitoring and enforcement functions b. which agency within the regulatory environment is best equipped to take on the lead role in relation to each function c. the identification of shared performance indicators, reporting arrangements and outcomes, where possible d. the creation of appropriate governance arrangements to support decision-making and performance monitoring. Subject to the outcome of the review, I recommend that the Director-General of the Department of Health: 7. Considers the development and documenting of a formal agreement setting out a clear statement of shared purpose and agreed roles and responsibilities of each of the agencies. 8. Ensures that MRQ, my office, AHPRA, QPS, the Office of the State Coroner, and Hospital and Health Services public health units communicates the agreed roles and responsibilities of each of their respective agencies clearly and regularly to all agency staff. 9. Reviews current resourcing levels and determines the resources required for MRQ to appropriately perform its functions. 10. Identifies *trigger points* for information sharing and referral between agencies in consultation with key agencies including MRQ, my office, AHPRA, QPS, the Office of the State Coroner and Hospital and Health Services public health units. 11. Directs MRQ to review its compliance and enforcement framework and to undertake a current risk assessment of work practices, including surveillance thresholds and criteria, at regular, prescribed intervals.
3. **Policies and procedures**	I recommend that the Director-General of the Department of Health: 12. Directs MRQ to review its existing documentation and develop a consolidated and current authoritative version of all policies and procedures.
4. **Communication and collaboration**	I recommend that the Director-General of the Department of Health: 13. Coordinates a consultation process to develop formal written multi-agency agreements that outline mechanisms for the exchange of information about

	schedule 8 medicine matters, and that these agreements include are requirement for regular review. 14. Coordinates regular formal liaison meetings between key stakeholders including my office, AHPRA, MRQ, the QPS and the Office of the State Coroner (at least every two months initially). 15. Explores changes to legislation to improve the ability of agencies involved in schedule 8 medicine management to share relevant and confidential information to improve the timeliness of risk mitigation strategies to ensure health and safety of the public.
5. **Real time prescription monitoring**	I recommend that the Director-General of the Department of Health: 16. Directs an expeditious review of Queensland Health's options for the introduction of a RTPM system in Queensland and the subsequent development of a business plan to progress the implementation of a RTPM system.

8.2 Recommendations monitoring plan

I have developed a recommendation monitoring plan (see appendix 7) to facilitate implementation of the recommendations arising from my investigation.

I note that, as a result of my consultation with stakeholders about my draft report, including my proposed recommendations, staff from the Department of Health have met with members of my staff to discuss actions that have been implemented, and are planned to be implemented, as a result of my investigation. Based on these discussions, I am of the view that the Chief Health Officer Branch is demonstrating a commitment to ensuring an effective and transparent regulatory framework for schedule 8 medicines in Queensland, as well as a willingness to work collaboratively with stakeholders to progress specific actions against the recommendations. I look forward to continued collaboration and, to this end, propose quarterly meetings between the two agencies.

Pursuant to s89(2) of the *Health Ombudsman Act 2013*, I request one (1) formal progress report, including documentation of the implementation status allocated by the Department of Health for each recommendation with supporting documentary evidence, to be provided to me by *30 June 2017*.

Leon Atkinson-MacEwen
Health Ombudsman

Appendix 1 Scheduling of medicines in Australia

Scheduling is a national classification system for controlling how all medicines for human therapeutic use—as well as veterinary, agricultural, domestic and industrial chemicals for which there is a potential risk to public health and safety—are made available to the public.

Medicines and chemical substances are scheduled according to the degree of risk and the level of control considered required over the availability of the medicine or chemical to protect public health and safety. The scheduling classification system underpins the need for particular health care professionals to be involved in the supply of certain medicinal substances in order to promote safe and quality use.

Provisions for the scheduling of medicines and chemicals are set out in the *Therapeutic Goods Act 1989* and associated regulations including the *Poisons Standard*[73].

The Poisons Standard

The *Poisons Standard* lists the decisions regarding the classification of medicines and poisons into schedules 1 through 9 according to increasingly restrictive levels of regulatory control.

Medical substances intended for human therapeutic use may be unscheduled or classified as:

- schedule 2 medicines—'pharmacy medicine', these may only be purchased at a pharmacy[74]
- schedule 3 medicines—'pharmacist only medicine', these may only be purchased at a pharmacy, where a pharmacist must personally hand the medicine to the recipient and give them an opportunity to seek advice
- schedule 4 medicines—'prescription only medicine', these may only be purchased with a prescription[75]
- schedule 5 medicines—'caution'
- schedule 6 medicines—'poison'
- schedule 7 medicines—'dangerous poison'
- schedule 8 medicines—'controlled drug', these prescription-only medicines have specific restrictions placed on their supply and use because of their dependence forming nature and high levels of misuse
- schedule 9 medicines—'prohibited substance'.

Schedule 2 and 3 medicines are often called *over-the-counter* medicines. Unscheduled medicines may be sold generally—for example, through supermarkets.

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[73] *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSMP; legally referred to as the *Poisons Standard)*. Most current version SUSMP No.6, 2015; The Poisons Standard is made under paragraph 52D(2)(b) of the *Therapeutic Goods Act 1989*

[74] In some states, Schedule 2 medicines may also be sold by licenced medicine sellers.

[75] This includes most medicines on the PBS.

Appendix 2 Actions taken by officers and list of information and documents obtained

The information obtained to inform my investigation was of both a quantitative and qualitative nature. During the investigation, my officers:

- examined relevant sections of the *Health Act 1937,* Health (Drugs and Poisons) Regulation 1996, Health Regulation 1996 and *Drugs Misuse Act 1986 (Qld*)
- undertook face-to-face consultations with a number of key stakeholder agencies and organisations who could contribute opinion and factual information relevant to the scope of the investigation
- examined data routinely collected by stakeholders
- reviewed formal submissions received from key stakeholders, which included comment on
  - the effectiveness of Queensland's current legislative and regulatory framework for monitoring of, and responding to, prescribing and dispensing of schedule 8 medicines by health practitioners
  - omissions or gaps existing in Queensland's current legislative and regulatory framework concerning monitoring of, and responding to, prescribing and dispensing of schedule 8 medicines by health practitioners
  - potential changes to Queensland's current legislative and regulatory framework to improve the monitoring of, and response to, prescribing and dispensing of schedule 8 medicines by health practitioners
  - potential measures—other than legislative and regulatory changes—that could be introduced to enhance monitoring of, and responding to, prescribing and dispensing of schedule 8 medicines by health practitioners
  - factors that support effective collaboration between agencies involved in the regulation of scheduled medicines and/or responding to concerns about inappropriate prescribing or dispensing of schedule 8 medicines by health practitioners
  - challenges in working with other agencies involved in the regulation of scheduled medicines and/or responding to concerns about inappropriate prescribing or dispensing of schedule 8 medicines by health practitioners
- examined internal policies, procedures, guidelines, work instructions, and template documents provided by key stakeholders such as MRQ
- assessed data on the extent of legitimate and illicit use of schedule 8 medicines
- considered existing documents that govern information sharing between relevant agencies, such as memorandums of understanding
- undertook background research into issues raised in consultations and submissions, including reviewing information available on the public record
- considered a sample of cases examined by my office which raised concerns about the effectiveness and efficiency of the monitoring of, and responses to, prescribing and dispensing of schedule 8 medicines by health practitioners.

Medicines Regulation and Quality

Written submission from Medicines Regulation and Quality, including:

- List of reports of stolen, forged or fraudulent prescriptions 2010-15
- List of Pharmacy Alerts sent 2010-15
- General Principles – Enforcement Intervention Matrices
- Health (Drugs and Poisons) Regulation 1996 Compliance Plan 2015-17
- Fax Template: Surveillance – Prescriber
- Fax Template: Surveillance – QOTP Prescriber
- MODDS Status Reports 2010-15
- Review of Drugs of Dependence Unit (the Foy Review) – April 1995
- Review of the Medical Board of Queensland's mechanisms for dealing with drug-impaired practitioners (the Siggins Miller Report) – March 2002
- Drugs of Dependence Unit Audit – Summary of Findings for Discussion – 2007
- Ministerial Briefing Note: External Audit of Drugs of Dependence Unit – 2007
- Response to Operational Audit of Drugs of Dependence Unit – November 2007
- Audit Report: Operational Audit of Drugs of Dependence Unit – June 2007
- Delegations by Positions: Health (Drugs and Poisons) Regulation 1996
- Enforcement Intervention Matrix: Health Act 1937
- General Principles – Enforcement Intervention Matrices
- Draft Statewide Compliance Plan 2015-16 and 2016-17
- User Operations Manual: DDU Alerts System
- MRQ Fact Sheet - Alprazolam Rescheduling
- MRQ Fact Sheet - Sell to ships master
- MRQ Fact Sheet - Ships master obligations
- MRQ Fact Sheet - Dispensing quantity and frequency of Drugs of Dependence
- MRQ Fact Sheet - Targin
- MRQ Fact Sheet - Ceasing hard copy/paper S8 prescriptions
- Application Form: Amendment of an approval
- Application Form: Approval for an organisation providing commercial paramedic services
- MODDS Internal Approval Request Form
- Approval Process (Mine sites & island resorts)

- Consent to Share Information (MRQ)
- Coroners Form 25 Response Cover Letter/Template
- Delegation Procedure for Public Health Acts
- Doctor Review Template
- Evidence Transfer Form
- Controlled Drugs Destruction Form
- Drug Therapy Protocol - Indigenous Health Working - Isolated Practice Area
- Drug Therapy Protocol - Midwives
- Drug Therapy Protocol - Pharmacist - Opioid Treatment Program
- Drug Therapy Protocol - Rural and Isolated Practice Area - Endorsed Nurse
- Endorsement Restoration Letter Template
- Endorsement Surrender Template
- MRQ Investigations Officer Procedures - December 2014
- Application for Licence (HDPR)
- Application for Licence (Wholesale Representative)
- OHO Cover Letter Template
- Optometry Board of Australia - Guidelines for Use of Scheduled Medicines
- Pharmacy Alert Template
- Prescribing for Family Member Letter Template
- Purchase Order (for scheduled drugs and/or poisons)
- Application for regulated restricted medicines
- Application for scheduled medicines
- Application Form - Qualifications (minimum qualification requirements)
- Approval to treat Drug Dependent Persons
- Treatment Report/Approval Form
- Application for research or teaching
- Warrant cover sheet
- HDPR Guideline - Animal management and/or welfare
- Application for animal management and/or welfare
- HDPR Guideline - Scheduled medicines at an island resort
- Application for scheduled medicines at an island resort

- HDPR Guideline - Scheduled medicines at a mine site
- Application for scheduled medicines at a mine site
- HDPR Notification Form (discrepancy, loss or theft of scheduled medicines)
- Workplace Instruction Appendix 5: Guide for conditions on approvals
- Workplace Instruction: Drug Treatment Approval for treatment with: Controlled Drugs, Restricted Drugs, Restricted Drugs of Dependency and Specified Condition Drugs
- Workplace Instruction: Criteria for assessing person's drug dependence status
- Workplace Instruction Appendix 4: Interim approval to prescribe a controlled drug to a drug dependent person while awaiting registration onto QOTP or ATODS review
- Workplace Instruction Appendix 2: Renewal of approval, guide for treatment of drug dependent persons
- Workplace Instruction Appendix 1: Guide to issuing approval for drug dependent persons
- Workplace Instruction Appendix 3: Guideline for issue of Section 78 approvals (Adult ADHD)
- Workplace Instruction Appendix 3: Guideline for issue of Section 78 approvals (ADHD in child under four years of age)
- Workplace Instruction: Guideline for issue of Section 78 approvals
- Workplace Instruction Appendix 3: Guideline for issue of Section 78 approvals (Idiopathic Hypersomnolence)
- Workplace Instruction Appendix 3: Guideline for issue of Section 78 approvals (Treatment Resistant Depression)
- XVT Solutions Real-Time Recording and Reporting of Controlled Drugs
- Controlled Drug Recording and Monitoring System: High Level Business Requirements Specification
- Controlled Drug Reporting and Monitoring System: Gap Analysis – October 2014
- Policy Paper: Centralised versus Distributed Model for the Electronic Recording and Reporting of Controlled Drugs System
- Application Architecture: Community Pharmacy Branch Electronic Recording and Reporting of Controlled Drugs
- ERRCD Operations and Governance Issues Diagram
- ERRCD Change Control Process Diagram
- Intermediate Level Requirements Specifications: Community Pharmacy Branch Electronic Recording and Reporting of Controlled Drugs
- Brief for Ministerial Correspondence: Implementation f the Electronic Recording and Reporting of Controlled Drugs in Queensland
- Project Memorandum: MODDS Replacement

- Controlled Drug Reporting and Monitoring System Gap Analysis – July 2014
- PowerPoint Presentation: Regulation of medicines, poisons and therapeutic goods in Queensland
- Medicines Regulation and Quality Organisational Structure Diagrams

Queensland Police Service

Written submission from the Queensland Police Service, including:

- QPS - A Guide to the Common Pharmaceuticals of Misuse
- QPS – Methods used to unlawfully obtain pharmaceuticals
- QPS – Common guide to the common pharmaceuticals of misuse
- QPS - Drug Investigations: Operational Assistance Kit (OAK)
- QPS- Operational Procedures Manual
  - Section 1.9: Release of information
  - Section 1.9.3 Request by members of the public and external organisations for information contained in QPRIME occurrences
  - Section 1.9.14 Requests for information from other government departments, agencies or instrumentalities
  - Section 1.9.15 Requests for information from other law enforcement agencies
  - Section 1.9.21 Release of information to health practitioner registration boards
  - Section 2.1 Investigative Process – Introduction
  - Section 2.5.1 Investigation – Introduction
  - Section 2.6.14 Joint investigations with external agencies
  - Section 2.17.9 Department of Human Services (Centrelink, Medicare and Child Support)
  - Section 2.17.12 Requesting information from Queensland Health
  - Section 3.4.1 Prosecution Process - Introduction;
  - Section 3.4.2 The decision to institute proceedings
  - Section 3.4.3 Factors to consider when deciding to prosecute;
  - Section 3.4.12 Drug exhibits
  - Section 3.4.16 Disclosure to courts of convictions closed under the Criminal Law (Rehabilitation of Offenders) Act
  - Section 3.4.32 Prosecuting authority to notify Chief Executive about committal, conviction etc. under the Public Service Act
  - Section 4.10 Drug matter

- Section 4.10.3 Analysis/examinations (other than Cannabis)
- Section 4.10.10 Application of Sections 130, 131 and 131A of the Drugs Misuse Act
- Section 8.1 Introduction
- Section 8.4 Death investigations
- Section 8.5.3 Health care related deaths
- Section 8.5.10 Deaths occurring as a result of a reportable event
- Section 8.5.16 Deaths in care
- Section 8.5.17 Suspected drug overdoses
- Section 11.20 Other Commonwealth matters and agencies

Pharmacy Guild of Australia

Written submission from The Pharmacy Guild of Australia, including:

- Sample documents demonstrating the Queensland Branch of the Pharmacy Guild's information sharing processes with the Australian Health Practitioner Regulation Agency (AHPRA), MRQ and/or the Queensland Police Service
- Pharmacy Guild of Australia's Quality Care Pharmacy Program (QCPP)
  - Section P1A: Confidentiality Policy
  - Section P2A: Dispensing
  - Section P2B: Brand substitution policy
  - Section P2J: Return of unwanted medicines
  - Section P7D: Incident reporting
  - Section P8A: Undertaking department stock
  - Section P11F: Deliveries by pharmacy staff
  - Section T1A: Legal Professional obligations
  - Section T1B: Self assessment checklist
  - Section T3A: Opioid substitution program checklist
  - Section T3B: Dose administration aids
  - Section T7C: Incident register
  - Section T7D: Incident report
  - Section T8A: Stock consumable checking schedule
  - Section T11A: Deliveries register

- Contact Information: Regulation of S8 drugs, QOTP and patient specific enquiries, and Electronic Lodgement of S8 prescriptions
- MRQ Fact Sheet: Ceasing hard copy / paper submission of schedule 8 medicine prescriptions
- Queensland Health Procedure: Destruction of Controlled Drugs – March 2012
- Queensland Health Form – Controlled Drugs for Destruction
- Sample Controlled drug register pages
- Queensland Health Public Health Unit Contact Details
- Consultation Feedback Template: Medicines, Poisons and Therapeutic Goods Bill 2014
- Electronic Reporting and Recording of Controlled Drugs Fact Sheet
- Summary of member responses to survey questions – Effectiveness of the Queensland regulatory system for schedule medicines

Hospital and Health Services

Written submissions from the following Hospital and Health Services:

- Central Queensland Hospital and Health Service
- Children's Health Queensland Hospital and Health Service
- Darling Downs Hospital and Health Service
- Mackay Hospital and Health Service
- Metro North Hospital and Health Service
- Metro South Hospital and Health Service
- Torres and Cape Hospital and Health Service
- South West Hospital and Health Service
- Sunshine Coast Hospital and Health Service
- West Moreton Hospital and Health Service

Australian Health Practitioner Regulation Agency

Written submission from the Australian Health Practitioner Regulation Agency

Appendix 3 Considerations in conducting the investigation

Rationale for the investigation

Prior to the commencement of this investigation, my office had commenced a number of separate investigations into allegations of inappropriate prescribing and dispensing of medicines in Queensland by registered practitioners, in particular medicines known as schedule 8 drugs or controlled drugs.

A preliminary review of these cases by my staff identified recurring concerns about the effectiveness of current processes, and associated information flows, for monitoring the prescribing and dispensing of schedule 8 medicines in Queensland. This included the:

- apparent failure to identify non-compliance by healthcare practitioners with their reporting and approvals obligations regarding ongoing prescribing and dispensing of schedule 8 medicines
- timeliness of responses to non-compliance once identified
- appropriateness of responses to identified non-compliance, including enforcement actions
- gaps in information provision between relevant stakeholders.

Prior to my investigation commencing, I undertook consultation with a number of key stakeholders to determine the final scope of my investigation.

A note on terminology

Terms used to describe substances that are subject to regulatory control due to their dependence forming nature and potential for misuse include schedule 8 drugs, schedule 8 poisons, controlled drugs, controlled medicines, drugs of dependence and drugs of addiction. In my report, I have used the term schedule 8 medicines to acknowledge the important and legitimate therapeutic use of schedule 8 substances, while also recognising that my investigation focused on only those medicines listed on schedule 8 of the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSMP; legally referred to as the *Poisons standard*[76]) in Australia.

Terms used to refer to the use of substances for a purpose not consistent with legal or medical guidelines include harmful use, misuse (intentional or unintentional), abuse, extramedical use, dependence and addiction. I have used the term misuse to reflect that, although the user may have medically driven reasons for using the medicine, the pattern of use has an increased risk of physical, mental and/or psychosocial problems.

People who visit multiple prescribers for obtaining numerous prescriptions for the same or similar medicines have traditionally been described as *doctor shoppers*. I have chosen to use the term *prescription shoppers* to reflect my focus on prescription medicines and acknowledge the increasing range of professionals who are able to prescribe schedule 8 medicines.

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[76] Most current version SUSMP No.6, 2015; The Poisons Standard is made under paragraph 52D(2)(b) of the *Therapeutic Goods Act 1989*

Appendix 4 List of guidelines

A number of other professional groups such as the Royal Australian College of General Practitioners and the Pharmaceutical Society of Australia also produce guidance documents to support safe, quality health care that include coverage of medicine safety. For example, criterion 5.3.1 of the *Standards for General Practice* covers safe and quality use of medicines, including prescribing, dispensing and administering. Similarly, Domain 4 of the *National Competency Standards Framework for Pharmacists in Australia* covers the review and supply of prescribed medicines.

In addition to these more general documents, professional bodies and expert groups have developed a range of guidelines to support health practitioners meet expected standards of practice for the quality use of schedule 8 medicines, in particular opioid analgesics and benzodiazepines.These include:

- *Prescription Opioid Policy: Improving management of chronic non-malignant pain and prevention of problems associated with prescription opioid use*[77]
- *Recommendations regarding the use of Opioid Analgesics in patients with chronic Non-Cancer Pain*[78]
- *Prescribing drugs of dependence in general practice*[79]
  - *Part A: Clinical Governance Framework*
  - *Part B: Benzodiazepines*
  - *Part C: Opioid Prescribing*[80]
- *Guidelines for use of benzodiazepines in psychiatric practice*[81]
- *Guidelines for use of dexamphetamine and methylphenidate in adults*[82]
- *Guidelines for use of scheduled medicines*[83]
- *Queensland Opioid Treatment Program: Clinical Guidelines*.[84]

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[77] The Royal Australasian College of Physicians, Australian and New Zealand College of Anaesthetists Faculty of Pain Management, The Royal Australian College of General Practitioners & The Royal Australian and New Zealand College of Psychiatrists. (2009). Prescription Opioid Policy: Improving management of chronic non-malignant pain and prevention of problems associated with prescription opioid use. Sydney. Available at: http://www.fpm.anzca.edu.au/resources/professional-documents/documents/Prescription%20Opioid%20Policy.pdf [Accessed September 2015]

[78] Australian and New Zealand College of Anaesthetists Faculty of Pain Management. (2015). Recommendations regarding the use of Opioid Analgesics in patients with chronic Non-Cancer Pain. Sydney:ANZCA. Available at: http://www.fpm.anzca.edu.au/resources/professional-documents/documents/PM1%202010.pdf [Accessed September 2015]

[79] The Royal Australian College of General Practitioners. Prescribing drugs of dependence in general practice. RACGP. Available at: http://www.racgp.org.au/your-practice/guidelines/drugs-landing/ [Accessed September 2015]

[80] Development of this section of the guide has commenced, with resources to be made available in late 2016.

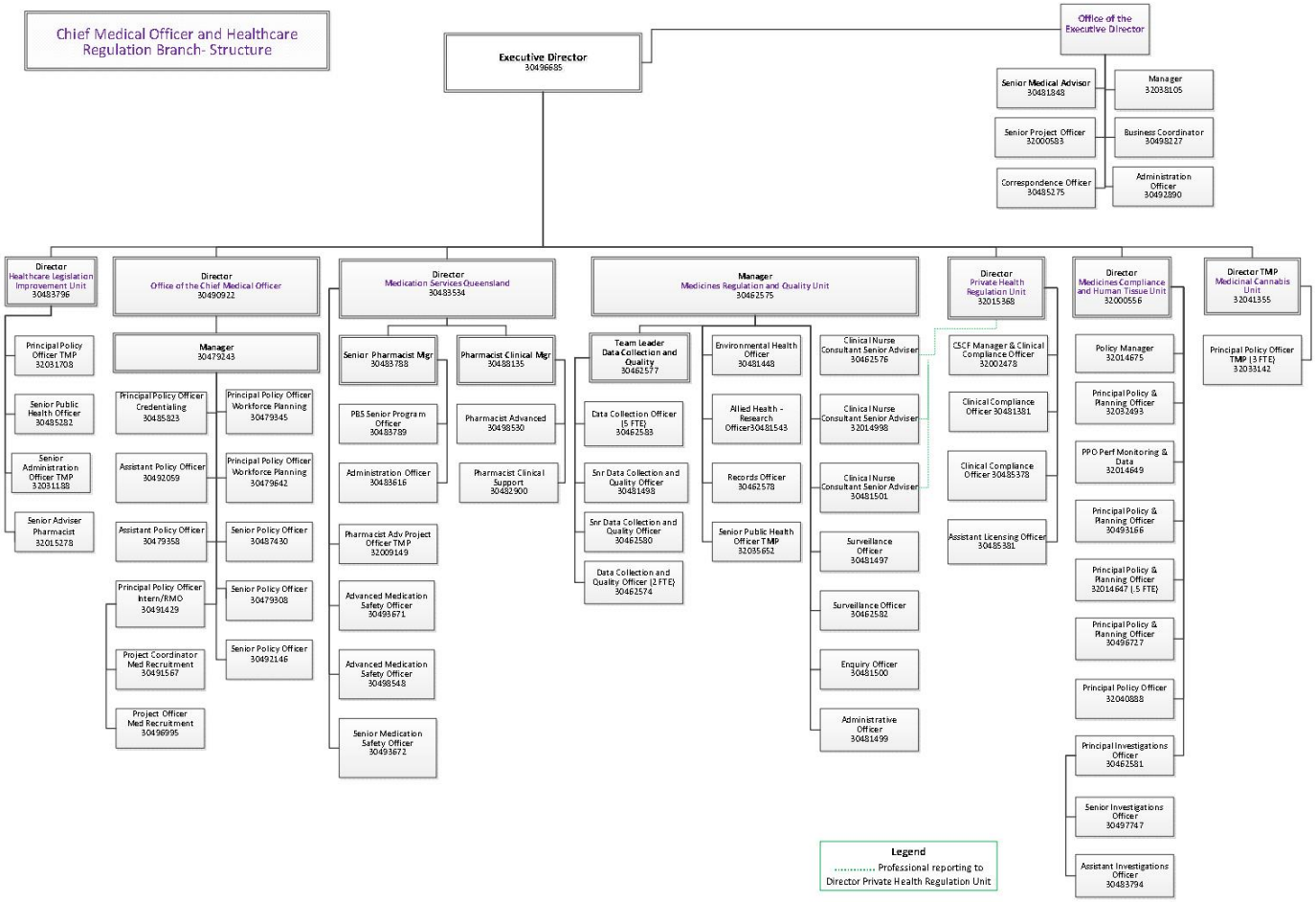
[81] The Royal Australian and New Zealand College of Psychiatrists. (2008) Practice Guideline #5: Guidelines for use of benzodiazepines in psychiatric practice. Available at: https://www.ranzcp.org/Files/Resources/College_Statements/Practice_Guidelines/pg5-pdf.aspx [Accessed September 2015]

[82] The Royal Australian and New Zealand College of Psychiatrists. (2009) Practice Guideline #6: Guidelines for use of dexamphetamine and methylphenidate in adults. Available at: https://www.ranzcp.org/Files/Resources/College_Statements/Practice_Guidelines/pg6-pdf.aspx [Accessed September 2015]

[83] Optometry Board of Australia. (2014). Guidelines for use of scheduled medicines. Available at: http://www.optometryboard.gov.au/documents/default.aspx?record=WD14%2f15745&dbid=AP&chksum=Sz7QDOlIiqlL0oeQrKy1NQ%3d%3d [Accessed September 2015]

[84] Queensland Health. (2012). Queensland Opioid Treatment Program: Clinical Guidelines 2012. Available at: https://www.health.qld.gov.au/publications/clinical-practice/guidelines-procedures/medicines/drugs-of-dependence/qotp-clinical-guidelines.pdf [Accessed September 2015].

Appendix 5 New Chief Medical Officer and Healthcare Regulation Branch structure



Appendix 6 Department of Health enforcement intervention matrixes

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GENERAL PRINCIPLES
ENFORCEMENT INTERVENTION MATRICES

Rationale

Medicines and poisons legislation recognises that medicines and poisons are potentially dangerous, and can be harmful or fatal if not manufactured, supplied and used safely and in accordance with their intended purpose. In addition, if medicines are not used by appropriately-trained professionals, the medicines will not have their intended therapeutic effect. Certain medicines can also be diverted for abuse or for the illicit drug trade

The Department of Health is obliged to regulate Medicines & Poisons to improve safe and effective use of Medicines & Poisons in Queensland. In partnership with manufacturers, distributors, health professionals and the public, Queensland Health seeks to encourage the appropriate use of scheduled medicines and protect the public from harms associated with inappropriate use.

The framework for medicines and poisons regulation is based on the relevant strategic and compliance plans and is intended to achieve the following outcomes;

1. The quality of the product along the supply chain (Proper Product)
2. No diversion (Proper Access)
3. That only people with the appropriate competencies use/access the substances (Proper Person)
4. That those that are accessing the product are doing it properly (Proper Use)

In the Health Protection and the Health Care Regulation Units, the enforcement process is applied by:

- investigating non-compliance, and determining the level of risk of the matter which is the subject of the complaint/audit/other intelligence source
- identifying the enforcement options in each investigation using a risk based enforcement tool to determine and record the most effective and consistent means of rectifying identified non-compliance with the legislation
- commencing the decided enforcement option
- reviewing decisions as part of an on-going improvement strategy.

The following provides decision makers with a tool to guide consistent and supported enforcement actions to rectify identified non-compliance with the *Health (Drugs & Poisons) Regulation, 1996*.

Compliance and enforcement activities under Queensland's public health legislation are essential to maintain and improve the health of members of the public by reducing their exposure to risks associated with food, tobacco, scheduled drugs and poisons and environmental hazards.

The compliance and enforcement options available to Queensland Health under this Regulation include:

- educative and advisory actions to inform of legislative obligations
- the issue of verbal and/or written advices or directions;
- the issue of compliance or improvement notices;
- the institution of legal proceedings (prosecutions); and
- administrative law action against licensees or the holders of statutory endorsements (eg. doctors, pharmacists).

Incorporated entities and individuals who are subject to the requirements of public health legislation have a responsibility to ensure compliance with relevant Acts and Regulations. The matrices reflect interventions that are considered appropriate, based on the relative risk of the identified non-compliance.

Authorised persons can choose one or more options based on the:

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- individual circumstance(s).
- advice contained in the relevant Enforcement Matrix;
- contents of state-wide enforcement policy and procedures; and

When considering the appropriate intervention, a **risk assessment** should be undertaken to determine the appropriate response. Risk assessment is a continuous process throughout the progression of the investigation. As further information is gathered, a more accurate assessment may be made about the level of risk and the appropriate enforcement intervention.

An important component of assessing any risk is consideration of the organisational risk posed by the alleged breach and a proposed course of action.

The attached tables list default interventions for responding to alleged breaches of public health legislation. The matrices have been developed to provide:

- a guide for decision-making and actions by authorised persons when undertaking enforcement options
- consistent application of compliance and enforcement options to best achieve organisational objectives; and

It is important to remember that the enforcement options outlined in the attached enforcement matrices are a guide only. Enforcement responses are subject to officer discretion and the exercise of appropriate principles of good administrative decision making and should take into account the particular and individual circumstances of the situation and the roles and actions of other regulating authorities.

COMPLIANCE ACTION INTERVENTION

		Consequence - Impact on human/animal health *Actual or potential as measured by maximum penalty for breach*				
		Level 1 ***Minor consequence***	**Level 2**	**Level 3**	**Level4**	**Level 5** *Major consequence*
Likelihood of non-compliance Based on compliance history, willingness and capacity to comply	**Category A** *High compliance*	Advice/education	Advice/education	Advice/education	Warning Letter Compliance Notice	Formal Warning Compliance Notice
	Category B	Advice/education	Advice/education	Advice/education Warning letter	Warning letter Compliance Notice	Formal Warning Compliance Notice
	Category C	Advice/education	Advice/education Warning letter	Warning letter Compliance Notice	Warning letter Compliance Notice	Prosecution Suspension Cancellation of Endorsement
	Category D	Advice/education Warning letter	Warning letter Compliance Notice	Formal Warning Compliance Notice	Formal Warning Compliance Notice	Prosecution Suspension Cancellation of Endorsement
	Category E *Low compliance*	Warning letter Compliance Notice	Warning letter Compliance Notice	Formal Warning Compliance Notice	Prosecution Suspension Cancellation of Endorsement	Prosecution Suspension Cancellation of Endorsement

The following tables should be referred to assist in assessment of compliance interventions in relation to the categories/levels referred to in the above tool.

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Likelihood of non-compliance

Likelihood Category	General Descriptor
A	Rare likelihood of non-compliance – No previous known occurrences of non-compliance Good demonstrated awareness and capacity to meet regulatory requirement Regulated entity ha a reasonable and cooperative attitude to compliance
B	Unlikely likelihood of non-compliance – Few previous known occurrences of non-compliance Questionable awareness and capacity to meet regulatory requirement
C	Possible likelihood of non-compliance – Numerous previous known occurrences of non-compliance Little or no demonstrated willingness or capacity to meet regulatory requirement
D	Likely likelihood of non-compliance – Wilful violation of regulatory requirements Little or no demonstrated willingness or capacity to meet regulatory requirement
E	Almost certain likelihood of non-compliance – Wilful violation of regulatory requirements Little or no demonstrated willingness or capacity to meet regulatory requirement Hindering or obstructing a departmental officer Refusing to provide required information Intentionally providing false or misleading information

Consequence

Consequence level	General Descriptor	Nature of offences
1	Very low consequence – Non-compliance that does not result in any immediate human health impact Minor administrative non-compliance No organisational and regulatory scheme risk	no evidence of health impacts on humans/animals no evidence of systematic failure of drugs and poisons governance or controls by endorsement holders. minor administrative oversights & shortcomings, infrequent failure to complete forms, make reports no risk of diversion of drugs & poisons, evidence of limited diversion (eg, incomplete prescription details, failure to report 2 month tx on CDs)
2	Low consequence – Non-compliance resulting in a minor, temporary threat to human health Moderate administrative non-compliance Negligible organisational and regulatory scheme risk	no evidence of health impacts on humans/animals no evidence of systematic failure of drugs and poisons governance or controls by endorsement holders. moderate administrative oversights & shortcomings, low frequency of failure to complete forms, make reports limited risk of diversion of drugs & poisons, evidence of limited diversion (eg, failure to seek approval for P/stims use in Adult pts)
3	Moderate consequence – Non-compliance resulting in a moderate, temporary threat to human health Major administrative non-compliance Moderate organisational and regulatory scheme risk	Limited evidence of health impacts on humans/animals possible evidence of systematic failure of drugs and poisons governance or controls by endorsement holders. moderate administrative oversights & shortcomings, high frequency of failure to complete forms, make reports moderate risk of diversion of drugs & poisons, evidence of limited diversion (eg, failure to submit dispensed CD Rxs, failure to seek approval for RDD, CDs in DD pts)
4	High consequence – Non-compliance resulting in a significant threat to human health Significant organisational and regulatory scheme risk	High risk of multiple health impacts on humans/animals some evidence of multiple health impacts on humans/'animals systematic or deliberate administrative failures moderate to high risk of diversion of drugs & poisons, evidence of limited diversion (eg, Rxing CD/RDDs for DD pts despite advice, inadequate storage of S7 poisons)
5	Extreme consequence – Known or likely human health impact that is severe in effect (e.g. hospitalisation and/or chronic health	known multiple health impacts on humans/animals high risk or evidence of large scale diversion of drugs and poisons, systematic failure of drugs and poisons governance or controls by

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Consequence level	General Descriptor	Nature of offences
	problems) Extremely high organisational and regulatory scheme risk	endorsement holders evidence of access by non-endorsed parties (eg, impaired health practitioner, high volume CD/RDD Rxs to DD pts despite advice & evidence of harms, advertising of S7 poisons in domestic setting, hawking activities))

Appendix 7 Recommendations monitoring plan

OHO case number: 201502155-RA1

Facility/entity name: Department of Health

	Investigation recommendation	Evidence requested to demonstrate implementation	Progress report 1 Due date
	I recommend that the Director-General of the Department of Health continues to actively consult with stakeholders on the proposed new framework for the regulation of medicines, poisons and therapeutic goods in Queensland, in particular in relation to the prescribing and dispensing of schedule 8 medicines.	▪ Submission outlining consultation plan or evidence of other actions taken and/or planned to obtain feedback from stakeholders on the draft Medicines, Poisons and Therapeutic Goods Bill 2015 and associated regulations, including details of current status	30 June 2017
	I recommend that the Director-General of the Department of Health takes into account the issues identified in this report in his consideration of the proposed new legislation.	▪ Submission outlining the Department of Health's progress and/or intentions about responding to the issues identified in this report regarding the new legislative framework.	30 June 2017
	I recommend that the Director-General of the Department of Health, following the introduction of the new Medicines, Poisons and Therapeutic Goods Act, ensures that Queensland Health works closely with stakeholders—including national health practitioner boards, QPS, professional associations and organisations such as the Private Hospitals Association	▪ Submission outlining the education program and strategies implemented and/or planned to ensure all stakeholders are aware of their obligations under the new legislation, including details of current status.	30 June 2017

	Investigation recommendation	Evidence requested to demonstrate implementation	Progress report 1 Due date
	of Queensland—to implement a tailored education program aimed at each stakeholder group to ensure all are aware of their obligations under the new legislation.		
	I recommend that the Director-General of the Department of Health ensures MRQ continues and strengthens its work with the QPS to ensure adequate guidance is provided to QPS officers about the misuse of scheduled medicines and the availability of various charges, as well as the practical consequences of bringing charges under a particular Act.	▪ Evidence of strategies and activities undertaken by MRQ to ensure QPS officers are provided with adequate information about the misuse of scheduled medicines and the availability and consequences of various charges under the different relevant Acts.	30 June 2017
	I recommend that the Director-General of the Department of Health considers recommending to the Queensland Minister for Health to propose at the next Australian Health Ministers' Conference that amendments are made to the National Law to require practitioners disclose to their national board if the practitioner has been charged or convicted of an offence under drugs and poison legislation, whether in a participating jurisdiction or elsewhere.	▪ Evidence of escalation of Recommendation 5 to the Queensland Minister for Health, and a copy of any response.	30 June 2017
	I recommend that the Director-General of the Department of Health establishes a committee to undertake a review of the roles and responsibilities of MRQ in light of the roles and responsibilities of the	▪ Copies of Terms of Reference, membership, meeting schedules, agenda papers and minutes of Committee meetings	30 June 2017

	Investigation recommendation	Evidence requested to demonstrate implementation	Progress report 1 Due date
	other agencies involved in regulating schedule 8 medicines. The review committee should include representatives from all key stakeholder groups including MRQ, my office, AHPRA, QPS, the Office of the State Coroner and Hospital and Health Service public health units. This review should consider: a. whether MRQ maintain each of its administrative, educative, therapeutic, and monitoring and enforcement functions b. which agency within the regulatory environment is best equipped to take on the lead role in relation to each function c. the identification of shared performance indicators, reporting arrangements and outcomes, where possible d. the creation of appropriate governance arrangements to support decision-making and performance monitoring.	▪ Details of the outcomes of the review, including steps taken by the Department of Health to address the issues put forward for the Committee to consider.	
	Subject to the outcome of the review, I recommend that the Director-General of the Department of Health considers the development and documenting of a formal agreement setting out a clear statement of	▪ Copy of the formal agreement developed, including any documents that outline the roles and responsibilities of the key stakeholder agencies including MRQ, the Medicines Compliance and Human Tissue Unit, the Office of the Health Ombudsman, AHPRA, QPS, the Office of the State	30 June 2017

	Investigation recommendation	Evidence requested to demonstrate implementation	Progress report 1 Due date
	shared purpose and agreed roles and responsibilities of each of the agencies.	Coroner, and Hospital and Health Services public health units and any other agencies with responsibilities in relation to schedule 8 medicines.	
	Subject to the outcome of the review, I recommend that the Director-General of the Department of Health ensures that MRQ, my office, AHPRA, QPS, the Office of the State Coroner, and Hospital and Health Services public health units communicates the agreed roles and responsibilities of each of their respective agencies clearly and regularly to all agency staff.	▪ Evidence that demonstrates that the Department of Health has confirmed with all stakeholder agencies that they have communicated the agreed roles and responsibilities of their agency to staff.	30 June 2017
	Subject to the outcome of the review, I recommend that the Director-General of the Department of Health reviews current resourcing levels and determines the resources required for MRQ to appropriately perform its functions.	▪ A detailed submission outlining – the scope, methodology and timeframe of the review – a copy of any report and any recommendations arising from the review – Details of the current implementation status of the recommendations.	30 June 2017
	Subject to the outcome of the review, I recommend that the Director-General of the Department of Health identifies *trigger points* for information sharing and referral between agencies in consultation with key agencies including MRQ, my office, AHPRA, QPS,	▪ A detailed explanation of trigger points identified for information sharing and referral between agencies.	30 June 2017

	Investigation recommendation	Evidence requested to demonstrate implementation	Progress report 1 Due date
	the Office of the State Coroner and Hospital and Health Services public health units.		
	Subject to the outcome of the review, I recommend that the Director-General of the Department of Health directs MRQ to review its compliance and enforcement framework and to undertake a current risk assessment of work practices at regular, prescribed intervals.	▪ Copy of correspondence from the Director-General to MRQ regarding the requirement to: – review its compliance and enforcement framework – undertake regular risk assessments. ▪ Evidence of planned or conducted follow-up by the Director-General with MRQ on the implementation of this requirement.	30 June 2017
	I recommend that the Director-General of the Department of Health directs MRQ to review its existing documentation and develop a consolidated and current authoritative version of all policies and procedures.	▪ Copy of correspondence from the Director-General to MRQ regarding the requirement to conduct a review and consolidate policy and procedure documents. ▪ Evidence of planned or conducted follow-up by the Director-General with MRQ on the implementation of this requirement. ▪ Evidence to demonstrate MRQ's compliance with this requirement e.g. list of all documented policies and procedures for MRQ and the Medicines Compliance and Human Tissue Unit, including most recent date of review.	30 June 2017
	I recommend that the Director-General of the Department of Health coordinates a consultation process to develop formal written multi-agency agreements that outline mechanisms for the	▪ An explanation of the consultation process developed and multi-agency stakeholders identified. ▪ An action plan and/or timeframes for the development of multi-agency agreements.	30 June 2017

	Investigation recommendation	Evidence requested to demonstrate implementation	Progress report 1 Due date
	exchange of information about schedule 8 medicine matters, and that these agreements include are requirement for regular review.	▪ Copies of all formal written multi-agency agreements that have been developed, or have been identified for development, including details of date of effect and review schedule.	
	I recommend that the Director-General of the Department of Health coordinates regular formal liaison meetings between key stakeholders including my office, AHPRA, MRQ, the QPS and the Office of the State Coroner (at least every two months initially).	▪ Copies of Terms of Reference, membership, meeting schedules, agenda papers and minutes of meetings.	30 June 2017
	I recommend that the Director-General of the Department of Health explores changes to legislation to improve the ability of agencies involved in schedule 8 medicine management to share relevant and confidential information to improve the timeliness of risk mitigation strategies to ensure health and safety of the public.	▪ Evidence of any actions taken by the Director-General to explore changes to legislation to improve timeliness of risk mitigation strategies.	30 June 2017
	I recommend that the Director-General of the Department of Health directs an expeditious review of Queensland Health's options for the introduction of a RTPM system in Queensland and the subsequent development of a business plan to progress the implementation of a RTPM system.	▪ Submission outlining the scope and methodology of the review into options for the introduction of a RTPM system in Queensland. ▪ A copy of any report and/or recommendations arising from the review.	30 June 2017

	Investigation recommendation	Evidence requested to demonstrate implementation	Progress report 1 Due date
		▪ A copy of business plan to progress the implementation of a RTPM system.	

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