Supplementary report

Undoing the knots constraining medicine regulation in Queensland

December 2018

Office of the HEALTH OMBUDSMAN

Listen. Respond. Resolve.

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About this report

This supplementary report has been prepared by Mr Andrew Brown, the Health Ombudsman for Queensland, outlining his findings in relation to the implementation of recommendations following the Office of the Health Ombudsman's investigation into the regulation of the prescribing and dispensing of schedule 8 medicines in Queensland.

Acronyms and abbreviations

AHPRA	Australian Health Practitioner Regulation Agency
Bill	(Draft) Medicines and Poisons Bill
CMOHR	Chief Medical Officer and Healthcare Regulation Branch (Queensland Health)
HDP	*Health (Drugs & Poisons) Regulation 1996* (Qld)
MCHT	Medicines Compliance and Human Tissue Unit (Queensland Health)
MOU	Memorandum of understanding
MRQ	Medicines Regulation and Quality (Queensland Health)
OHO	Office of the Health Ombudsman
RTPM	Real time prescription monitoring

Executive summary

On 17 March 2015 the then Health Ombudsman initiated an investigation into the appropriateness and effectiveness of the regulatory system for prescribing and dispensing schedule 8 medicines[1] and associated risk to public health and safety. The Office of the Health Ombudsman's (the office) *Investigation report: Undoing the knots constraining medicine regulation in Queensland*[2] was finalised in November 2016.

The investigation report made 16 recommendations proposing solutions and risk mitigation strategies associated with five particular areas of concern or 'knots'. The Director-General, Queensland Health accepted all 16 of the report's recommendations and has provided regular progress updates to the office on the implementation of the recommendations.

I am satisfied all 16 recommendations have been either fully implemented or are in progress and dependent on the passing into legislation of a draft Medicines and Poisons Bill (the Bill) and accompanying regulation.

This supplementary report provides a snapshot of the current landscape of schedule 8 medications in Queensland, highlighting key initiatives and activities implemented since the 2016 investigation in response to the recommendations. This report also considers the impact of anticipated legislative change and the introduction of real time prescription monitoring (RTPM) on the use and regulation of scheduled medicines in Queensland.

Key initiatives implemented by Queensland Health in response to the OHO investigation report have included the development of:

- a draft bill and regulation to address the specific issues identified in the investigation report
- a business case for a real time reporting solution for Queensland
- improved risk identification and escalation strategies to support more appropriate prescribing and dispensing practices by health professionals
- interagency liaison processes to identify trigger points for information sharing and referral between agencies, resulting in a draft memorandum of understanding (MOU)[3].

Further, taking into account the progress on a draft bill and regulation and support for an RTPM system in Queensland, I consider it vital that all stakeholders are suitably prepared for this changing landscape and continue to understand their roles and responsibilities within this context.

In particular, I encourage the Director-General to continue to lead improvement by:

- providing operational guidance to departmental staff through a planned and structured approach to prioritising and developing supporting policies

[1] Schedule 8 medicines are prescription only medicines that have specific restrictions place upon their supply and use because of their dependence-forming nature and high levels of misuse.
[2] Available on the Office of the Health Ombudsman website at www.oho.qld.gov.au.
[3] MOU is between AHPRA, the Health Ombudsman, the Queensland Police Service and Queensland Health.

- resourcing and prioritising the education for health practitioners to ensure they are aware of their legal obligations under the new legislation to ensure safe prescribing and dispensing of schedule 8 medicines in Queensland
- continuing to coordinate regular interagency meetings to address the new monitoring and enforcement issues, challenges and trends which will emerge in response to the new legislation and RTPM
- utilising the full range of enforcement actions available—specifically prosecution of health practitioners who are repeatedly non-compliant with regulations for prescribing and dispensing of schedule 8 medicines—to improve regulatory compliance and increased public health and safety.

The implementation of the recommendations has improved regulatory agencies' understanding of their mutual roles, responsibilities and relationships. It is imperative this understanding continues to evolve as the regulatory environment changes. I have extended an invitation to continue to work with Queensland Health to support the health and safety of Queenslanders during this transition period.

Andrew Brown
Health Ombudsman

Background

In November 2016 the office published a report following an investigation into regulatory responses to prescribing and dispensing of schedule 8 medicines that posed a risk to the health and safety of the public in Queensland.

The principal objectives of the investigation were to identify and assess:

- the appropriateness and effectiveness of agencies with key regulatory roles in monitoring and responding to concerns about prescribing and dispensing of schedule 8 medicines within health services—taking into account current and proposed legislative and regulatory frameworks and best practice approaches
- 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
- 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
- the effectiveness of current practices for monitoring, enforcing and improving the appropriate use of schedule 8 medicines.

In examining the regulatory framework for schedule 8 medicines in Queensland, the investigation report highlighted a number of areas of actual or potential risk largely arising from an uncoordinated approach to medicine regulation across various government departments.

The investigation report methodology was underpinned by Malcom Sparrow's problem-solving approach to minimising harm, which identifies patterns of risk or 'knots' when investigating the issues (with issues being categorised by the knot to which they relate). The investigation report made 16 recommendations (see appendix 1) that identified the critical components associated with five specific knots and was crafted to support an appropriate level of collaborative intervention that would facilitate the undoing of the knots one by one[4].

The recommendations primarily focused on areas of legislative complexity, RTPM, cross-agency roles and responsibilities, policies and procedures, and communication and collaboration.

[4] Sparrow, M 2008, *The character of harms: operational challenges in control*, Cambridge University Press, Cambridge.

Monitoring the implementation of recommendations

The office monitors all recommendations made in its public reports. This provides independent oversight of the implementation of the recommendations and assures the public that, once a potential area of risk is identified, it will be actively monitored to ensure it is effectively addressed.

Monitoring program

The investigation report included a recommendation monitoring plan that outlined expectations regarding implementation and monitoring activities by the office, requiring the submission of a progress report and quarterly meetings between Queensland Health and the office.

The office received two comprehensive progress reports from the Director-General, Queensland Health, containing an explanation and evidence of actions taken by Queensland Health towards implementing the 16 recommendations. Following consultation with Queensland Health, the office is in agreement that 13 recommendations have been *fully implemented* and three have been *partially implemented* (see appendix 2).

Undoing of the knots

Unravelling a knot can require an innovative and agile approach. The following section explores how the knots constraining medicine regulation in Queensland have been unravelled.

The knots, as identified in the original investigation report, are:

- legislative complexity
- real time prescription monitoring
- agency roles, responses and functions
- policies and procedures (incorporated within agency roles, responses and functions within this supplementary report)
- communication and collaboration.

Legislative complexity

The original investigation report highlighted the legislative complexity impacting the management of schedule 8 medicines at the time and discussed specific legislative limitations of the current regulatory framework (knot 1). It also noted a new regulatory regime had been proposed by Queensland Health that sought to repeal the current legislation[5] and replace it with a new Medicines, Poisons and Therapeutic Goods Act and Regulation. Following consultation and feedback during 2014 and 2015, a draft bill was developed, however the accompanying draft regulation had not been released for consultation at the time of the report.

[5] This included the *Health Act 1937*, the *Health Regulation 1996* and *Health (Drugs and Poisons) Regulation 1996*.

Since then, Queensland Health has implemented a program of stakeholder consultation on the draft Bill (formerly the Medicines, Poisons and Therapeutic Goods Bill 2015) and draft regulation. Importantly, the draft Bill has captured and addressed the specific individual issues identified in the investigation report.

The Director-General advised the office in March 2018 that consultation on the draft legislation would commence with key stakeholders in June 2018. This includes consideration of legislative amendments to allow for real time monitoring of the prescribing and dispensing of schedule 8 medicines. The draft of the Bill is open for consultation and Queensland Health have indicated that it will be introduced to parliament in 2019.

Findings

At present, suitable regulatory change is proceeding. I note that two recommendations remain in progress[6] and are on track to be fully implemented. This will occur when the proposed Bill is passed into legislation in a form that addresses the recommendations in the investigation report and a subsequent education program commences.

I acknowledge that education under the current regulatory system remains an ongoing need amongst clinicians. Since the investigation report was published, the Chief Medical Officer and Healthcare Regulation (CMOHR) branch has implemented initiatives to improve access to information about schedule 8 medicines by clinicians, including the transition of Medicines Regulation and Quality's (MRQ) telephone support and enquiry service to the schedule 8 Enquiry Service—13S8INFO.[7] This service is now hosted by Health Support Queensland's Health Contact Centre, with specialised support provided by MRQ.

While these initiatives are positive improvements, there is still potential to increase the educative role of MRQ. This was highlighted in Coroner James McDougall's published inquest findings from May 2018 that considered the widespread issues associated with the growing misuse of opioid prescription medication in Queensland and, more broadly, Australia. Coroner McDougall noted that '[Queensland Health] is of the view that improved telephone access system enquiry service, will allow doctors to get better and timelier access to clinical and regulatory advice in these matters'.[8] However, he also recommended Queensland Health 'should urgently consider what additional steps can be taken to educate general practitioners and pharmacists as to the scope and functions of MRQ, particularly the availability of advice as to appropriate prescribing practices'.

As acknowledged by Coroner McDougall, the improvement measures implemented by Queensland Health 'are not sufficient to address the flaws in the present monitoring system, nor a suitable substitute for a real time prescription monitoring system in Queensland'.[9] I support Coroner McDougall's comments and recommendation to promote the functions and services provided by Queensland Health to educate

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[6] Recommendations 1 and 3.
[7] Queensland Health 2018, *Enquiry service for clinicians*, viewed 12 July 2018, <https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/medicines/drugs-of-dependence/clinician-enquiry>.
[8] Coroner James McDougall 2018, *Inquest into the death of William John House, Vanessa Joan White, Jodie Anne Smith; and Daniel Keith Milne*, 21 May, Coroners Court of Queensland, Southport,, p. 98.
[9] Coroner James McDougall 2018, *Inquest into the death of William John House, Vanessa Joan White, Jodie Anne Smith; and Daniel Keith Milne*, 21 May, Coroners Court of Queensland, Southport, p.107.

and support clinicians to meet their obligations under the *Health (Drugs & Poisons) Regulation 1996* (HDP Regulation).[10]

The Director-General has advised my office that the education program—combining information, communication and support materials—will be undertaken when the proposed Bill has passed through parliament to ensure parties are aware of their legal obligations under the new legislation. This is necessary to promote safe prescribing and dispensing of schedule 8 medicines and I would encourage Queensland Health to continue to prioritise this in rolling out the new regulatory framework.

Real time prescription monitoring

Since the investigation report's publication, support has continued to grow for a national RTPM system that electronically collects information about the prescriber, dispenser, patient, and relevant drugs at the time of dispensing. Significantly, health ministers at the April 2018 Council of Australian Government's Health Council meeting 'agreed to progress national real time prescription monitoring as a federated model with jurisdictions committed to progressing development and adaptation of systems to connect to and interface with Commonwealth systems to achieve a national solution'.[11]

The roll-out of the real time drug monitoring initiative—the Electronic Recording and Reporting of Controlled Drugs—was announced by the Australian Government in 2010 with the state of Tasmania the first to adopt the system using the secure webpage based remote access system DORA.[12] Other states and territories are at different stages of adopting and implementing RTPM systems. New South Wales implemented a customised version of the national system in 2016 with the capability to enable RTPM.[13] Western Australia has commenced a staged transition to the national system that is expected to be completed by late 2018[14] and the Australian Capital Territory has recently introduced legislation to implement electronic recording and reporting using the DORA platform.[15] More recently, Victoria has developed and implemented its own mandatory RTPM system known as SafeScript following the passing of legislation in late 2017.[16]

The Director-General advised the office in March 2018 that options for a RTPM are under consideration.

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[10] The HDP Regulation sets out regulatory controls around the use of controlled (scheduled) drugs in Queensland.
[11] COAG Health Council 13 April 2018 (corrected 16 April 2018), Communique.
[12] Peter Boyles (Chief Pharmacist) 2016, *DORA – Drugs and Poisons Information System Online Remote Access*, fact sheet, February, Tasmanian Government, viewed 12 July 2018, <http://www.dhhs.tas.gov.au/psbtas/publications/general/dora>.
[13] Julie Lambert 2017, *Victoria goes it alone on real time monitoring*, The Medical Republic, viewed 11 July 2018, <http://medicalrepublic.com.au/victoria-goes-alone-real-time-monitoring/10450>.
[14] Somerville, J 2017, 'Real time prescription monitoring – what does it mean for health professionals?', *Pharmacy Insights*, February 2017, viewed 15 June 2018, <https://www.meridianlawyers.com.au/insights/real-time-prescription-monitoring-mean-health-practitioners/>.
[15] Fitzharris, M (ACT Minister for Health and Wellbeing) 2018, *Prescription monitoring to help protect Canberrans from misuse of drugs*, media release, 10 May, Australian Capital Territory Government, viewed 11 July 2018, <http://www.cmd.act.gov.au/open_government/inform/act_government_media_releases/meegan-fitzharris-mla-media-releases/2018/prescription-monitoring-to-help-protect-canberrans-from-misuse-of-drugs>.
[16] Paola, S 2017, 'Real-time script monitoring laws pass parliament', *AJP.com.au*, 19 October, viewed 15 June 2018, <https://ajp.com.au/news/real-time-script-monitoring-laws-pass-parliament/>.

Findings

The value and benefits of a fully mandated and integrated system capable of accessing real time information nationally, appears to be many years away due to the inconsistent roll-out of RTPM systems across the country and a lack of federal oversight or input into the development of these systems.

Despite this, I am reassured by Queensland's recent progress towards an RTPM system and the Health Minister's reinforced commitment toward support for a federated approach to this issue.

An innovative intervention such as RTPM will continue to require multiple agencies and organisations to work in collaboration to ensure that the potential benefits of RTPM are maximised.

I consider the recommendation to review RTPM options and develop a business plan to progress implementation in Queensland has been fully implemented. I understand the SafeScript RTPM system introduced in Victoria allows prescription records for all schedule 8 medicines and some schedule 4 (S4) medicines[17] to be transmitted in real time. I am not party to the considerations regarding an RTPM system in Queensland, however I strongly support the inclusion of restricted schedule 4 drugs of dependence for monitoring, to minimise the increasing risk of these medications to the community.

The expeditious transition toward a statewide RTPM system with the capability to monitor schedule 8 and restricted schedule 4 drugs of dependence—and possibly feed into a national system in the future—is a vital element of a contemporary and safe health system in Queensland. This approach also aligns with the government's strategy for *My health, Queensland's future: Advancing health 2026*,[18] which positions innovation and the implementation of smart technology as a key focus area. I fully endorse the Minister and Queensland Health's continued commitment to RTPM.

Agency roles, responses and functions

In knot 2 and 3 in the investigation report, it was determined that effective regulatory action was significantly hindered by a lack of clarity regarding the roles and responsibilities of the different parties involved in regulating schedule 8 medicines in Queensland. The report drew specific attention to the inadequate operational guidance provided to Queensland Health staff charged with delivering agency responses, which led to confusion about standards of practice and resulted in inadequate responses to issues relating to prescribing and dispensing of schedule 8 medicines.

To address these issues, Queensland Health has collaborated broadly on improvement initiatives (discussed below) to the existing regulatory systems to support more appropriate prescribing and dispensing practices, and identified trigger points for information sharing and referral between agencies, until an RTPM system is introduced in Queensland. Queensland Health established a Schedule 8 Strategic Oversight Committee to oversee the development and implementation of these initiatives under the authority of the Director-General.

Membership of the Schedule 8 Strategic Oversight Committee is comprised of the following individuals and agency representatives:

- Chief Health Officer, Queensland Health (chair)

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[17] Schedule 4 medicines monitored by SafeScript Victoria includes all benzodiazepines (such as diazepam), 'Z-drugs' (such as zolpidem), quetiapine and codeine.
[18] Queensland Health 2016, *My health, Queensland's future: Advancing health 2026*, Queensland Government, Brisbane, <https://www.health.qld.gov.au/__data/assets/pdf_file/0025/441655/vision-strat-healthy-qld.pdf>.

- Queensland Police Service
- Australian Health Practitioner Regulation Agency (AHPRA), Queensland
- Coroners Court of Queensland
- Executive Director, CMOHR branch, Queensland Health
- Office of the Health Ombudsman.

As noted in the investigation report, an internal realignment of the CMOHR branch functions commenced mid-2016, resulting in MRQ no longer having primary responsibility for the monitoring and enforcement of prescribing, dispensing and use of schedule 8 controlled drugs and some schedule 4 restricted drugs of dependency in Queensland. Consequently, there has been an increase in the number of CMOHR branch units having responsibilities for the use and regulation of schedule 8 medicines;[19] MRQ has retained the administrative, educational and therapeutic functions associated with monitoring and now focuses on approvals, licenses, clinical advice and education to medical practitioners regarding the HDP Regulation.

The Medicines Compliance and Human Tissue Unit (MCHT unit) in Queensland Health was established under this realignment and is responsible for investigating all incidences of alleged non-compliance in relation to part 3 and part 9 of the HDP Regulation. In addition to this enforcement function, this unit shares the monitoring function with MRQ. The MCHT unit recently recruited a manager. The investigations team now includes four full time investigations staff and one principal policy and planning officer.

A comprehensive review was also undertaken by the CMOHR branch of the Schedule 8 Compliance and Enforcement Framework (the framework) which provides an overarching policy position and articulates how Queensland Health enforces its regulatory responsibilities. The revised framework describes a focus on compliance monitoring and a risk-based response to regulation relative to the seriousness of the non-compliance. [20]

In revising the framework, the CMOHR branch has:

- modified the monitoring reports generated from the Monitoring of Drugs of Dependence System[21] to both encourage and assist compliance with the HDP Regulation and take enforcement action where appropriate
- introduced a risk assessment process that occurs at multiple decision points
- identified information sharing decision points throughout the evidence gathering and investigation process with the office and AHPRA.

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[19] Five units within the CMOHR branch have a role in the use and regulation of medicines: MRQ, the MCHT unit, Medication Services Queensland, Healthcare Legislation Improvement Unit and Medicinal Cannabis Unit.
[20] Queensland Health 2017, *The Schedule 8 Medicines Compliance and Enforcement Framework draft for consultation*, June, Queensland Government, Brisbane.
[21] Queensland Health collates schedule 8 medicines dispensing data for the state via the Monitoring of Drugs of Dependence System. Dispensing data was previously provided to MRQ by public and private dispensers within 14 days of the end of each month. Since the introduction of new legislation, from 1 October 2017 pharmacies are required to provide schedule 8 medicine dispensing reports weekly. This information captures all schedule 8 medicines dispensed as a result of individual and the Queensland Opioid Treatment Program prescriptions, with the exception of schedule 8 medicines administered within hospital settings.

Additionally, in articulating this approach the CMOHR branch has also sought to work with other statutory agencies to identify trigger points for information sharing and referral between agencies while discharging their respective functions. An information sharing and enforcement decision flowchart has been developed by the MCHT unit, AHPRA and the office. This flowchart is referenced in the framework and identifies communication and referral points for disclosure of information (within the limitations of existing legislation) to AHPRA and the office during the enforcement escalation process. For example, a voluntary notification by the MCHT unit to the office may be triggered under sections 144 and 145 of the *Health Practitioner Regulation National Law (Queensland) 2009* during the MCHT unit's preliminary assessment stage when an alleged non-compliance with the HDP Regulation is identified. This trigger point is an example of a 'work around' that enables information sharing between agencies within the confines of existing legislative and privacy provisions.

The internal realignment of departmental resources and engagement with statutory agencies has enabled a purposeful separation of regulatory actions and facilitated clearer operational guidelines to be articulated in the framework.

The CMOHR branch has also undertaken a review of all policy documentation as recommended in the investigation report; however at the time of the second progress report in March 2018, the CMOHR branch had not finalised a consolidated and up-to-date authoritative version of all policies and procedures. The Director-General advised the office that a range of current policy documents to support the implementation of the framework and provision of information from the Monitoring of Drugs of Dependence System have been developed, providing guidance regarding monitoring and compliance activities. Further, policy documentation had not been progressed due to the impending changes that will be required as a result of the implementation of the proposed Bill and RTPM system.

Findings

The investigation report made seven recommendations aimed at clarifying the roles, responsibilities and functions of participants in this regulatory space. Queensland Health has demonstrated a commitment to implementing the recommendations resulting in greater clarity and delineation of agency roles and avenues for communication and interface.

I note however that one of these seven recommendations regarding the review of MRQ and the MCHT unit's policies and procedures remains only partially implemented.[22] I accept that further changes to policies and procedures will be required as a result of the implementation of the proposed Bill and RTPM system, however this does not exempt Queensland Health from the need to provide a consolidated and authoritative version of documents to provide guidance to staff on current operational processes and requirements. I strongly support a planned and structured approach to prioritising the full and complete implementation of this recommendation.

I am reassured by the CMOHR branch's risk-based approach to compliance and enforcement evident in the revised framework. Specifically, one positive improvement is the framework's focus on the more effective use of allocated resources to focus on the monitoring of the Monitoring of Drugs of Dependence System data and to develop and implement clear thresholds on how to escalate a matter appropriately.

[22] Recommendation 12: I recommend that the Director-General of Queensland Health directs MRQ to review its existing documentation and develop a consolidated and current authoritative version of all policies and procedures.

My office has seen a notable increase in notifications from the MCHT unit coinciding with Queensland Health's realignment and implementation of the framework. This has risen from less than five notifications per year to 13 notifications in 2016–2017, and 18 notifications in 2017–2018.[23] However, despite the separation of the enforcement function and an increase in resourcing to the MCHT unit, I am concerned with Queensland Health's lack of decisive and timely enforcement action in response to non-compliance with the HDP Regulation. My office has continued to see evidence of multiple warnings and compliance notices being issued to practitioners by MRQ and the MCHT unit in response to ongoing and repeated non-compliance with the HDP Regulation.

To my knowledge, Queensland Health's enforcement activities have resulted in a very limited number of suspensions or cancellations[24] of practitioner endorsement to undertake certain activities involving schedule 8 medicines.[25] I am unsure why this avenue of enforcement and other avenues of prosecution have not been pursued more robustly by Queensland Health and consider this a missed opportunity by the Chief Health Officer to send a message of deterrence to health practitioners who are not meeting their legislative obligations.

I strongly encourage the Director-General to continue to resource and support the fulsome implementation of the compliance and enforcement framework, utilising the full range of enforcement actions available under the current legislative framework.

Communication and collaboration

A lack of information sharing between agencies that deal with interrelated schedule 8 medicine matters was identified in the investigation report as posing a risk to public health and safety. The investigation report's recommendations focused on minimising the barriers and harms arising from this system, by developing formalised information exchange agreements, conducting regular stakeholder liaison meetings and exploring legislative change options to improve information sharing.

Under the Schedule 8 Strategic Oversight Committee's terms of reference, it was agreed a schedule 8 working group would be established to progress the recommendation to develop a formal agreement outlining mechanisms for information sharing about schedule 8 medicine matters. The working group is comprised of representatives from:

- CMOHR branch, Queensland Health
- AHPRA, Queensland
- Queensland Police Service
- Office of the Health Ombudsman.

At the time of the last progress report, the working group had captured information sharing capabilities and enforcement responsibilities of each of the agencies and had drafted an MOU between the agencies. The MOU was finalised on 4 October 2018 and outlines the respective roles and

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[23] Information on the number of notifications in 2016–2017 and 2017–2018 has been supplied by Queensland Health in the letter from Michael Walsh, Director-General, Queensland Health to Maurice Drake, Director, Compliance (appendix 3).
[24] Pursuant to section 24 of the HDP Regulation.
[25] Endorsement means any one of the following: an authority, an approval, a drug licence, a wholesale representative licence, a poisons licence, a cyanide permit

responsibilities of the parties in relation to protecting the public from risks associated with prescribing, dispensing, supplying, administering and use of both schedule 8 and schedule 4 drugs of dependence.

Importantly, the MOU:

- describes the shared purpose of the parties and commitment to cooperative action
- identifies the functions that overlap across three or more parties
- identifies each of the parties' legislative responsibilities
- acknowledges statutory requirements relating to information sharing by each party
- incorporates formalised governance processes to ensure regular review.

In addition to the working group, Queensland Health also established the schedule 8 interagency health liaison network in response to the then Health Ombudsman's opinion 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'. The network currently includes Queensland Health, AHPRA and the office, with representatives meeting regularly to share information and progress initiatives, including the information sharing and enforcement decision flowchart incorporated into the Schedule 8 Compliance and Enforcement Framework (discussed above).

Queensland Health advised in March 2018 that representation by the Queensland Police Service and Coroners Court of Queensland at the network meeting has not been required due to the current context of the issues being progressed.

Findings

I am impressed by the commitment and problem solving strategies demonstrated by the working group and network representatives toward unravelling this knot and am satisfied the three associated recommendations have been fully implemented.

The MOU will facilitate improved communication between regulatory agencies, consequently leading to improved risk responses and mitigation strategies in the management of schedule 8 and schedule 4 medicines. As a party to the MOU, I support the inclusion of schedule 4 drugs of dependence in the agreement to ensure the ongoing consideration and recognition of the risks associated with these restricted drugs.

The current legislative requirements surrounding disclosure of personal information continues to challenge agencies in their efforts to protect public health and safety. However, the formalised interagency liaison processes initiated by Queensland Health has resulted in improved information sharing between agencies in accordance with statutory, confidentiality and privacy obligations, enabling agencies to take relevant action to protect the public health and safety. I am aware Queensland Health has commenced a consultation process with parties—including my office—to enable appropriate confidentiality and information sharing provisions to be incorporated into the draft Bill. These provisions would be a welcome inclusion to address the current deficiencies in the system that are being temporarily resolved through the MOU.

I encourage the continuation of regular interagency meetings in consideration of the anticipated changing legislative environment and introduction of RTPM in Queensland. Continued liaison with all

statutory agencies and their continued participation in the network is critical to ensuring a comprehensive understanding of monitoring and enforcement issues, challenges, and emerging trends in Queensland.

Submission from Queensland Health

The office provided Queensland Health with a draft of this report prior to publication, inviting submissions about comments that could be seen as adverse. A summary of relevant information contained in the submission from Michael Walsh, Director-General, Queensland Health is included within appendix 3 of this report.

Conclusion

In examining the regulatory framework for managing safe and appropriate access to schedule 8 medications, the investigation report identified 16 recommendations to improve medicine regulation in Queensland. I am pleased to confirm that 13 of the recommendations have been fully implemented with two recommendations dependent on the proposed Bill passing into legislation and the roll-out of an education program. I encourage Queensland Health to prioritise the finalisation of policy and procedure documents to appropriately guide their staff in performing the relevant functions and ensure the full implementation of the final outstanding recommendation.

In monitoring the implementation of the recommendations my office has held the unique position of also being a party invested in working collaboratively with other regulatory agencies to undo the knots constraining medicines regulation in Queensland. I acknowledge the success of interagency collaboration in finding the pathways and mechanisms to successfully traverse and unravel the knots within this complex regulatory environment.

As Queensland progresses towards the implementation of a new regulatory scheme for medicines and poisons with the introduction of the proposed Bill, this report provides a timely snapshot of the current monitoring and enforcement landscape.

My findings have reinforced the need for effective communication and collaboration in building productive and efficient partnerships to support a complex regulatory environment. Queensland Health has demonstrated strong leadership in developing formalised mechanisms to improve information sharing and coordination of issues, particularly with defining the roles of responsibilities of the various agencies engaged in this jurisdiction. Given the benefits to date, the continuation of regular interagency liaison should have a core role in supporting a smooth transition during a period of regulatory change. Such liaison will enable the sharing of experiences and perspectives of the various agencies while allowing for the exploration and understanding of issues, challenges and emerging trends within this environment.

Additionally, I consider a renewed focus on current education and support for clinicians to meet their obligations under the current HDP Regulation is critical to effective regulation. I encourage the Director-General to suitably resource the roll-out and ongoing provision of comprehensive targeted training and education with the passing of the proposed Bill.

I also draw attention to applying and utilising the full range of enforcement actions available under the current regulatory regime in the interests of public safety. The prosecution of non-compliant health practitioners is a forceful and potentially highly effective mechanism for deterrence which has not been fully utilised to date. My office welcomes the opportunity to work with Queensland Health to explore this

avenue of intervention in the future. I will communicate further with the Director-General on the potential scope for this initiative.

The implementation of the recommendations has been instrumental in improving regulatory agencies' understanding of their mutual role and responsibilities and has improved relationships. The investigation report acted as a conduit to improve agency responsiveness to public health and safety, providing the framework to work collaboratively toward a successful transition and implementation of the MPB and RTPM, thereby advancing Queensland towards the government's 2026 goals.

Going forward, I endorse and encourage the prompt introduction and continued progress of the new legislative framework for the regulation of medicines and poisons in Queensland.

Appendix 1—Full list of recommendations

Knot	Recommendations[26]
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

[26] Recommendations from *Investigation report: Undoing the knots constraining medicine regulation in Queensland*. At that time the Coroners Court of Queensland was known as the Office of the State Coroner.

Knot	Recommendations[26]
	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 a requirement for regular review.

Knot	Recommendations[26]
	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.

Appendix 2—Recommendation status report

Recommendation	Progress report 1—June 2017	Progress report 2—March 2018
1	Partially implemented	Partially implemented
2	Partially implemented	Fully implemented
3	Not implemented	Partially implemented
4	Partially implemented	Fully implemented
5	Partially implemented	Fully implemented
6	Partially implemented	Fully implemented
7	Partially implemented	Fully implemented
8	Not implemented	Fully implemented
9	Partially implemented	Fully implemented
10	Partially implemented	Fully implemented
11	Partially implemented	Fully implemented
12	Partially implemented	Partially implemented
13	Partially implemented	Fully implemented
14	Partially implemented	Fully implemented

Recommendation	Progress report 1—June 2017	Progress report 2—March 2018
15	Partially implemented	Fully implemented
16	Partially implemented	Fully implemented

Appendix 3—Queensland Health submission summary

Michael Walsh, Director-General, Queensland Health

I support the conclusion that 13 of the 16 recommendations from the original report have been fully implemented and three recommendations have been partially implemented. Work will continue on the three remaining recommendations. I note the areas you have identified where continued improvement would be of benefit. Future work undertaken by the Queensland Department of Health will be mindful of your advice.

The Queensland Department of Health's commitment to improving the regulation of scheduled medicines is ongoing and I provide the following additional information to indicate further progress in implementing recommendations from the report:

- The draft Medicines and Poisons Bill and Regulation was circulated for targeted consultation on 19 September 2018. The consultation phase closed on 16 October 2018. It is anticipated the Bill and Regulation will be introduced into Parliament in 2019. The Queensland Department of Health acknowledges the importance of resourcing and prioritising the training for health practitioners to ensure they are aware of their obligations under the revised legislation. A comprehensive implementation plan includes communication and education for stakeholders about their obligations under the new legislative scheme.
- The draft Memorandum of Understanding referred to in the Supplementary Report was finalised on 4 October 2018.
- The Queensland Department of Health has committed to implement a program of work for a real-time prescription monitoring solution and associated strategies needed to support and embed the policy and culture change required to ensure the success of the program. The project will take a phased implementation approach. It is anticipated that the Information and Communications Technology solution and associated policy change will be established across Queensland by 2020 with the full program of work completed by 30 June 2021. The core project team will consist of one AO8 Project Manager, two AO7 Principal Project Officers and one AO5 Project Support Officer. Additional specialised staff will be recruited as required. The Project Manager has commenced employment on the project.

  The project will be governed by an oversight steering committee with advisory groups linked to key deliverables including:

  - Information and Communications Technology Solution (real-time reporting and visibility to prescribers, dispensers and regulators).
  - Policy reform (standards and regulations associated with new Medicines and Poisons Bill)
  - Engagement and Education (communication and education strategies to support the understanding and uptake of the real-time reporting system and policy reform).

  The Queensland Department of Health is commencing work to develop and implement a Real-Time Prescription Monitoring System.
- As indicated in the Supplementary Report, the Schedule 8 Enquiry Service – 13S8INFO is now hosted by the Health Contact Centre, Health Support Queensland. New legislation introduced from 1 October 2017 resulted in pharmacies being required to increase the frequency of

Schedule 8 controlled drug dispensing reports from monthly to weekly. This change was implemented to enable the provision of a more up to date prescribing history to doctors who contact 13S8INFO. Please note this update particularly in relation to footnote 21 on page 11 of the report.

- Funding allocated for 13S8INFO has been increased by $200,000 in 2018/19 to enable increased capacity. This will allow for promotion of the service and increased access for doctors to obtain up to date prescription information and regulatory advice. Promotion of the service will be linked to the new requirements in the Medicines and Poisons Act and the implementation of a real-time reporting system.
- The Queensland Department of Health has completed further work on policies and procedures for administering the current legislation. Further to the Supplementary Report, an additional organisational change was implemented from 1 July 2018 with the creation of the Healthcare Approvals and Regulation Unit, Chief Medical Officer and Healthcare Regulation Branch. This Unit has taken responsibility for managing applications, certain approvals and licenses relating to the use of scheduled medicines in Queensland under the Health (Drugs and Poisons) Regulation 1996 and the Public Health (Medicinal Cannabis) Regulation 2017. Documentation is being progressively updated where possible with a view to introduction of the new Medicines and Poisons Act.
- As indicated in the Supplementary Report, there will be significant change in the regulatory environment for scheduled medicines with the introduction of new legislation and a real-time reporting system. A complete review of all policies and procedures will be required as part of the implementation process for the new legislation and real-time reporting system. The Queensland Department of Health is committed to the need to provide a consolidated and authoritative version of documents to provide guidance to staff on operational processes and requirements and funding for this purpose has been factored into the project budget.

The Queensland Department of Health notes the comments in relation to utilising the full range of enforcement actions available under the current regulatory scheme in the interests of public safety. As indicated in the Supplementary Report, an internal realignment of functions within the Chief Medical Officer and Healthcare Regulation Branch was completed in mid-2016 resulted in the formation of the Medicines Compliance and Human Tissue Unit, Chief Medical Officer and Healthcare Regulation Branch. This separated the education and clinical advice function from the investigation and enforcement function. A Manager, Investigations has recently been recruited. The Investigations Team now includes four full-time investigation staff and one Principal Policy and Planning Officer.

There has been an increase in regulatory activity with ten warning letters, 13 compliance notices, one Show Cause Notice and three surrender of endorsements completed in 2017-18. The number of voluntary notifications to your office regarding health practitioners has increased from 13 in 2016-17 to 18 in 2017-18. It is noted that action was taken by the Australian Health Practitioner Regulation Agency following a number of these voluntary notifications. Concerns regarding a health service provider were also provided to your office which resulted in an interim prohibition order being placed on the health service provider.

A process for sharing information with the Queensland Police Service regarding concerns about unlawful activity due to patients attending multiple prescribers was also developed. Information was provided to the Queensland Police Service on four occasions in 2017-18.

Regulatory activity continues to increase in 2018-19 with seven compliance notices, three notices of proposed action, one cancellation of authority two Queensland Police Service notifications, one notification to the New South Wales Ministry of Health and five warning letters as at 19 October 2018. The Chief Medical Officer and Healthcare Regulation Branch is continuing to monitor the implementation of the Schedule 8 compliance and enforcement framework and will consider appropriate action on a case by case basis to improve regulatory compliance and increase public health and safety. The Queensland Department of Health will participate in ongoing stakeholder liaison meetings with your office to discuss this issue.

I concur with the view on the success of interagency collaboration to date and the need for ongoing information sharing and collaboration around issues identified during the implementation of the new legislation and real-time reporting system. The Queensland Department of Health will continue to coordinate quarterly Schedule 8 Health Liaison Group meetings with representatives from the Australian Health Practitioner Regulation Agency (AHPRA), your office and the Queensland Department of Health.