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THE LEGISLATIVE ASSEMBLY FOR THE

AUSTRALIAN CAPITAL TERRITORY

ACT GOVERNMENT RESPONSE TO CORONIAL RECOMMENDATIONS FROM THE INQUEST INTO THE DEATH OF LAUREN MAREE JOHNSTONE

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Executive Summary

On 4 June 2019, ACT Chief Coroner Walker delivered her report in response to the *Inquest into the death of Lauren Maree Johnstone*.

Chief Coroner Walker found Ms Johnstone died on 7 January 2015 from the combined toxic effect of prescription and non-prescription medications that were lawfully acquired. Ms Johnstone's death came about as a result of compliance with her prescribed medication regime aggravated by the addition of non-prescription medication without the prescriber's knowledge.

Chief Coroner Walker made eight recommendations. The recommendations that are applicable to the ACT Health Directorate (ACTHD) can be broadly grouped as follows:

- To expand the list of monitored medicines in the ACT to include schedule 3 (pharmacist only) and schedule 4 (prescription only) medicines,
- To mandate use of the DAPIS Online Remote Access (DORA) real time prescription monitoring website by health practitioners, and
- That functionality be added to DORA to highlight where a patient demonstrates drug-seeking behaviour.

In response to the recommendations of Chief Coroner Walker, the submission:

- Supports expanding the scope of monitored medicines to include specified Schedule 4 medicines, subject to the ACT's adoption of national Real Time Prescription Monitoring (RTPM) by June 2021 and stakeholder consultation on the scope of medicines to be monitored.
- Notes to recommendation mandating health practitioner use of DORA. Mandating the use of the ACT's monitored medicines database may be further considered following the ACT's adoption of national RTPM by June 2021 and assessed in a regulatory impact analysis.
- Supports including functionality within DORA to alert prescribers to potential drug-seeking behaviours. This recommendation has already been partially addressed in DORA. Additional functionality will be achieved through the ACT's adoption of national RTPM by June 2021.

Background

Medicines Scheduling

The Poisons Standard, as made under the *Therapeutic Goods Act 1989 (Cth)*[1], lists medicines in Schedules according to their risk to public health. The ACT adopts the Poisons Standard under the *Medicines, Poisons and Therapeutic Goods Act 2008*[2] (MPTG Act). The MPTG Act establishes local controls on the sale, supply, administration, use and prescribing of scheduled medicines.

A description of the four medicines schedules is as follows.

Schedule 2	**Pharmacy only medicines** that may require advice from a pharmacist to be used safely and are only available from a pharmacy.

[1] *Therapeutic Goods Act 1989 (Cth),* s52D(2)(b); Poisons Standard 2019 (Cth). Federal Register of Legislation.
[2] Medicines, Poisons and Therapeutic Goods Act 2008 (ACT), s 15

Schedule 3	**Pharmacist only medicines** that require advice from a pharmacist to be used safely and are available without a prescription.
Schedule 4	**Prescription only medicines** that are available from a pharmacy on prescription.
Schedule 8	**Controlled medicines** that have additional restrictions on their prescribing and supply to reduce abuse, misuse or dependence.

Controlled Medicines

Controlled medicines are those which are associated with an increased risk of abuse, misuse, dependency or diversion. Examples include morphine and oxycodone for the treatment of pain, methadone or buprenorphine for the treatment of drug-dependency or amphetamines for the treatment of Attention Deficit Hyperactivity Disorder.

Under the MPTG Act, prescribers must apply to the Chief Health Officer (CHO) for approval to prescribe a controlled medicine for each patient in circumstances of chronic or continuing treatment or where the patient is drug dependent. Approval applications are processed by delegates of the CHO in the Health Protection Service (HPS).

Evidence of harms

Harms arising from the abuse and misuse of prescription medicines are of growing concern nationally. Medicines of primary concern include opioid medicines and benzodiazepines, some antipsychotic medicines and antiepileptic medicines.

Over the past decade, drug-induced deaths were more likely to be due to prescription drugs than illicit drugs. The number of drug-induced deaths involving opioids has more than trebled in the last 10 years nationally[3]. In 2016, there were 663 drug-induced deaths where benzodiazepines were present, and 550 where 'other opioids' (Scheduled analgesic medicines such as oxycodone, morphine, and codeine) were present[4].

The ACT Government recognises the growing harms call for a co-ordinated response and actions by Australian governments. The *ACT Drug Strategy Action Plan 2018-2021*[5] includes priority action areas to address community harms due to illicit use of pharmaceuticals.

The ACT Government also has a focus on reducing medicine related harms through delivering effective regulatory services and improving systems under the MPTG Act. In 2016, the ACT Government introduced changes to regulation to improve the CHO approvals framework and minimise harms. This involved creation of more flexible Category Approvals for prescribers and establishing new evidence based Prescribing Standards that prescribers must adhere to. The ACT Government has also had a strong focus on prescription monitoring systems since 2014, which is explored in the next section.

[3] Penington Institute. Australia's Annual Overdose Report 2019. Melbourne: Penington Institute, 2019.
[4] Australian Institute of Health and Welfare 2017. Non-medical use of pharmaceuticals: trends, harms and treatment, 2006-07 to 2015-16. Drug treatment series no.30. Cat. no. HSE 195. Canberra: AIHW.
[5] ACT Drug Strategy Action Plan 2018-2021: A Plan to Minimise Harms from Alcohol, Tobacco and Other Drug Use. Available at https://www.health.act.gov.au/about-our-health-systempopulation-health/act-drug-strategy-action-plan

Monitored medicines database

The MPTG Act establishes provisions for the ACT's monitored medicines database. The purpose of the database is to collect and report information on the prescribing and dispensing of monitored medicines in the ACT.

The ACT's current database is the Drugs and Poisons Information System (DAPIS), used by the HPS since 2014. DAPIS is an important public health and regulatory tool used by the HPS to collect and record information about controlled medicine approvals issued by the HPS and prescriptions dispensed in pharmacies.

DAPIS is also able to analyse approvals and dispensing information to generate alerts to the HPS user for unauthorised supplies. The HPS monitors these alerts in order to detect and respond to public health risks including excessive supplies, prescription or 'doctor' shopping events for controlled medicines.

In 2018, over 185,000 controlled medicine prescriptions were dispensed in ACT pharmacies and reported to DAPIS. Of these the HPS processed over 34,000 DAPIS alerts triggered by unauthorised or excessive controlled medicine supplies. From those, the HPS sent over 2,400 monitoring letters to prescribers alerting them to potential concerns regarding their patient's treatment.

On 29 March 2019, the ACT's DAPIS Online Remote Access (DORA) platform was launched by the ACT Government. DORA is a secure real time prescription monitoring (RTPM) website that is an extension of DAPIS, and which allows prescribers and pharmacists to access information about controlled medicines approved and dispensed for ACT patients.

DORA has been introduced in the ACT to reduce the growing harms in the community associated with pharmaceutical abuse and misuse.

DORA was launched partly in response to an ACT Coroner's recommendation in 2017 that, "The *ACT Government implement Drug and Poisons Information System (DAPIS) and adopt the real time monitoring system known as DORA*". The recommendation was made in response to the *Inquest into the Death of Paul Fennessy*, who died in 2010 after ingesting an unknown quantity of prescription and/or illicit drugs which were partly obtained through doctor shopping activities.

DORA is intended to be a clinical support tool for prescribers and pharmacists, to enable them to better identify and manage patients who may be exhibiting signs of drug dependency or drug seeking behaviours, such as 'doctor shopping'.

The use of DORA by health professionals is not mandatory under the MPTG Act. The voluntary implementation of DORA by the ACT Government was modelled on Tasmania's use of DORA since 2011, which has been linked to a reduction in opioid related deaths in that jurisdiction from 33 deaths in 2007 to 15 in 2013[6].

[6] Reynolds A, Boyles P. Clinical care and regulation of opioid use. The Tasmanian model. *Medicine Today*. 2017; 18(3 Suppl)17-21.

The ACT Government is actively working with local key stakeholders to promote DORA's uptake. As of October 2019, 276 prescribers from key specialty areas (17.8 per cent of ACT AHPRA registered[7]) and 197 pharmacists (33.1 per cent of ACT AHPRA registered) have a DORA account.

Monitored Medicines

Under the MPTG Act, monitored medicines are defined as either controlled medicines or a medicine that is declared by the Minister to be a monitored medicine. The Minister may declare a medicine to be a monitored medicine if satisfied that the declaration is consistent with the purposes of the monitored medicines database. No Minister has ever declared any other medicines to be monitored in the ACT.

Reporting of information to the monitored medicines database

Under the MPTG Act, ACT pharmacies are required to report supplies of all monitored medicines to the CHO, which is recorded in the monitored medicines database. The CHO may also enter into an arrangement with another data source entity to collect and store information on the database.

The ACT is currently collecting pharmacy dispensing information for monitored medicines to DAPIS from the National Data Exchange (NDE). The NDE forms part of the national (RTPM) system developed by the Commonwealth. The NDE provides a real time dispensing event feed to DAPIS (and in turn DORA) for all controlled medicines dispensed from ACT pharmacies, as well as controlled medicines dispensed from interstate pharmacies for ACT residents.

Data from the NDE is sourced under terms of a Tripartite Agreement between the ACT Government, Commonwealth and vendor FRED IT Group, executed 31 May 2019.

Next steps: adoption of national RTPM

The ACT Government has committed to adopting the national RTPM system by June 2021.

The national RTPM system will deliver benefits over current ACT DAPIS and DORA by enabling health practitioners and regulators from across Australia to access a common prescription monitoring platform and enable data sharing between jurisdictions.

Adoption of national RTPM is consistent with the Council of Australian Governments Health Council agreement in April 2018 to progress national RTPM as a federated component model. The ACT's adoption of national RTPM is funded through the ACT Budget 2019-2020, totalling $2.1 million over two years.

The ACT's national RTPM project includes replacement of DAPIS, which is approaching end of life, as well as adoption of national RTPM features including a new health practitioner portal.

[7] Registration data obtained from the Medical Board of Australia Board Registrant Data 1 Oct 2018- 31 Dec 2018, the Nursing and Midwifery Board of Australia Board Registrant Data 1 July 2018- 30 Sept 2018 and the Pharmacy Board of Australia Board Registrant Data 1 Oct 2018- 31 Dec 2018.

Other jurisdictions

Currently, the only other Australian jurisdictions operating RTPM systems are Tasmania and Victoria. Tasmania adopts a voluntary approach to its DORA system and currently collects and displays all Schedule 8 medicines and all Schedule 4 opioids.

Victoria commenced implementation of its SafeScript® RTPM system in late 2018. Its use by prescribers and pharmacists will be mandated in April 2020[8]. SafeScript® currently collects and displays all Schedule 8 medicines, Schedule 4 benzodiazepines, Schedule 4 opioids, quetiapine, and 'Z-Class' sedative drugs.

The Queensland parliament passed a Bill in September 2019 to introduce a monitored medicines database that will include Schedule 8 and some Schedule 4 medicines. It is understood Queensland will implement the national RTPM system following passage of the Bill from 2020.

Discussion

In response to the *Inquest into the death of Lauren Maree Johnstone*, the ACT Coroner made several recommendations that relate to ACTHD. The recommendations were made on the basis that Ms Johnstone died from the combined toxic effect of prescription and non-prescription medications. The recommendations are as follows:

- that the Therapeutic Drugs Authority consider whether promethazine and doxylamine are appropriately scheduled in the Poisons Standard, or whether some further form of restriction to these medications having regard to the risk of misuse (including when taken in combination with other sedating medications) is warranted;
- that irrespective of the response of the Therapeutic Drugs Authority, the ACT Health Minister by instrument declare the following substances to be monitored medicines for the purposes of the DORA system: tramadol, doxylamine and diazepam;
- that the ACT Health Minister consider widening the scope of monitored medicines under the DORA system to include the entirety of medicines listed in Schedules 3 and 4 of the Poisons Standard;
- in the alternative, that the ACT Health Minister consider widening the scope of monitored medicines under the DORA system to include certain prescription and over-the-counter medications that may have significant sedating or other adverse effects when taken in combination with opioids or benzodiazepines;
- that the ACT Health Minister consider adding functionality to the DORA system to highlight where a patient has demonstrated drug-seeking behaviour, including but not limited to, when a patient has signed a medication contract;
- that the ACT Health Minister consider making access to and use of the DORA system mandatory for all ACT prescribing physicians and pharmacists prior to writing and/or dispensing prescriptions;

[8] Victorian Government Department of Health and Human Services. About SafeScript [Internet]. Victoria: Department of Health and Human Services; 2018. Available from: https://www2.health.vic.gov.au/public-health/drugs-and-poisons/safescript/about-safescript

- that the CAPS Clinic and Sole Vita Day Surgery alter its pre-admission forms to expressly prompt patients to list all over-the-counter medications they are either presently taking or take frequently, perhaps with examples of some common brand names;
- that the Royal Australian College of General Practitioners, the Australian and New Zealand College of Anaesthetists, and the Royal Australasian College of Surgeons all consider conducting information campaigns with their members to encourage specific prompting (verbally and on applicable forms) of patients on consumption of over-the-counter medications when taking a patient's history.

The key issues and conclusions by Chief Coroner Walker are as follows:

- The manner and cause of Ms Johnstone's death was the combined toxic effect of prescription and non-prescription medications including doxylamine, tramadol, codeine, oxycodone, zopiclone and fluoxetine.
- Ms Johnstone's death came about as a result of compliance with her prescribed medication regime aggravated by the addition of non-prescription medication without the prescriber's knowledge.
- Ms Johnstone's death was the unexpected result of self-administration of lawfully prescribed and obtained non-prescription medication.

Chief Coroner Walker's recommendations to Government may be grouped into three key themes as follows. Each of these will be addressed separately in this report.

- To expand the list of monitored medicines in the ACT to include schedule 3 (pharmacist only) and schedule 4 (prescription only) medicines,
- To mandate use of DORA by health practitioners, and
- That functionality be added to DORA to highlight where a patient demonstrates drug-seeking behaviour.

Expansion of the ACT's monitored medicines list

There is a growing body of evidence of harms including death arising from unintentional overdose due to the abuse and misuse of prescription and non-prescription medicines in Australia. In 2017, the Victorian Government commissioned a report into harms arising from schedule 4 (prescription only) medicines[9], which found significant harms from certain substances and led to the reporting of these medicines in Victoria. Since then, increasing trends of harm including death have been reported for prescription opioids, benzodiazepines, antipsychotic and antiepileptic medicines[10,11].

All other jurisdictions that have RTPM systems in place either currently collect, or plan to collect Schedule 4 medicines information in their respective RTPM systems. Specifically, these jurisdictions are Victoria, Tasmania and Queensland from 2020.

[9] Austin Health. Evidence to inform the inclusion of Schedule 4 prescription medications on a real-time prescription monitoring system. Austin Health, March 2017.
[10] Crossin R, et al. Pregabalin misuse- related ambulance attendances in Victoria, 2012–2017: characteristics of patients and attendances. *MJA* 2019; 210(2): 75-79.
[11] Penington Institute. Australia's Annual Overdose Report 2019. Melbourne: Penington Institute, 2019.

The ACT Government considers that expanding the range of monitored medicines to include some Schedule 4 medicines could deliver public health benefits through providing health practitioners with more information to assist in their making clinical decisions. This could potentially also provide a secondary benefit of assisting to influence DORA uptake and use by health practitioners.

Expanding the scope of monitored medicines for some Schedule 4 medicines will not add regulatory burden on health practitioners. Pharmacists will not be required to manually report additional information for new monitored medicines that are dispensed, as the information may be automatically collected from pharmacy dispensing systems via the NDE to DAPIS and DORA. Prescribers will not be required to seek CHO approval for schedule 4 monitored medicines.

The ACT is supportive of the Chief Coroner's recommendation to expand the scope of monitored medicines to include the Schedule 4 medicines tramadol and diazepam.

The ACT Government is also supportive of widening the scope of monitored medicines to include other Schedule 4 medicines, subject to consultation with key local stakeholders in 2020 on the scope of medicines to be monitored. ACTHD will subsequently provide recommendations to the Minister for Health to declare specified Schedule 4 medicines as monitored medicines under the MPTG Act.

The additional technology, notably improved data matching and filtering technologies, associated with the adoption of national RTPM will allow implementation of this recommendation in 2021, following the above consultation in 2020.

The ACT Government notes the Chief Coroner's recommendation to consider declaring Schedule 3 medicines (including doxylamine) as monitored medicines under the MPTG Act. The ACT Government considers this measure to be out of step with other jurisdictions and believes it would have a significant regulatory impact on health practitioners. Pharmacists would be required to commence recording of schedule 3 monitored medicines supplied to patients in their pharmacy practice systems, for information to be reported to the monitored medicines database via the NDE. Pharmacists are unlikely to support such a change.

The ACT Government supports the Therapeutic Goods Administration reviewing the potential health effects posed by specified over-the-counter medicines and consider if their scheduling status is appropriate. The ACT Government notes the Chief Coroner included in their recommendations to this inquiry that the Therapeutic Drugs Authority *[sic]* consider the scheduling of schedule 3 medicines promethazine and doxylamine.

Mandatory use of DORA by health practitioners

The ACT Government implemented DORA under the *Medicines, Poisons and Therapeutic Goods Amendment Act 2018* with the objective of providing practitioners with a voluntary tool to support patient care and reduce public health harms.

The ACT's implementation of DORA was modelled on Tasmania's voluntary use of DORA since 2011, which has been linked with a reduction in opioid related deaths. The ACT voluntary system was established also taking into account other pre-existing controls including:

- mandatory prescriber approvals prior to prescribing controlled medicines for continuing or chronic treatment, or for drug-dependent patients,
- mandatory pharmacy reporting for all supplies of controlled medicines to ACTHD, and
- active monitoring by ACTHD.

Mandating the use of DORA would add significant regulatory burden upon health practitioners. Changes to primary legislation would be required to require health practitioners to consider a person's prescription history in DORA before prescribing or dispensing monitored medicines. This would need to be subject to regulatory impact analysis and best considered in consultation with local stakeholders.

Systems limitations of DORA also present practical implementation barriers to mandating health practitioner use of DORA. The ACT Government considers that adoption of the national RTPM by 2021 presents a better opportunity to support health practitioners in the uptake and use of the database, as it includes fully electronic and integrated workflows with practice management systems, and improved user and login experiences.

The ACT has robust legislative controls to ensure the safe prescribing and supply of monitored medicines until such time the option to mandate RTPM systems in the ACT can be explored in full.

The ACT Government notes the Chief Coroner's recommendation to consider making access to and use of DORA mandatory for all ACT prescribing physicians and pharmacist prior to the writing and/or dispensing of prescriptions, but does not support taking steps to mandate the health practitioner use of DORA until such time as the ACT has adopted the national RTPM framework, and can fully assess the impacts of such a proposal in consultation with stakeholders.

The ACT Government will continue to work with local stakeholder groups and individual practitioners to encourage the uptake and use of DORA and national RTPM systems, with a view to maximising public health outcomes.

Additional DORA functionality

The ACT Government fully supports the Chief Coroner's recommendation that DORA be able to highlight to health practitioners where a patient is exhibiting drug-seeking behaviours.

DORA currently displays automated prompts against some patient profiles where additional care or treatment considerations might be warranted, including for patients who are approved to receive Opioid Maintenance Treatment. The HPS may also activate prompts within an individual's DORA profile where a patient is known to engage in drug-seeking behaviour and has been declared as drug-dependent by a treating doctor.

DORA does not currently have functionality to display where a patient has signed a medication contract, as suggested by the Chief Coroner.

Additional alert functionality will be achieved through the ACT's adoption of the National RTPM system by June 2021. Options to display where a patient has a signed ACT medication contract will also be explored when developing ACT business requirements for the national system.

Summary of responses to each recommendation

a) the ACT Health Minister by instrument declare the following substances to be monitored medicines for the purposes of the DORA system: tramadol, doxylamine and diazepam;

The ACT Government supports the Chief Coroner's recommendation that Schedule 4 medicines tramadol and diazepam be declared monitored medicines. ACTHD will prepare a declaration for the Minister that tramadol and diazepam become monitored medicines subject to the ACT's adoption of national RTPM by June 2021.

The ACT Government notes the Chief Coroner's recommendation to monitor the Schedule 3 medicine doxylamine, however does not intend to pursue this option due to the increased regulatory burden upon practitioners. The ACT Government considers it preferable for the Therapeutic Goods Administration to review the scheduling status of doxylamine.

b) that the ACT Health Minister consider widening the scope of monitored medicines under the DORA system to include the entirety of medicines listed in Schedules 3 and 4 of the Poisons Standard;

The ACT Government supports the Chief Coroner's recommendation to monitor some medicines listed in Schedule 4 of the Poisons Standard.

The ACT Government supports that some Schedule 4 medicines with known harms due to abuse and misuse be monitored medicines, subject to the ACT's adoption of national RTPM by June 2021.

The ACT Government will undertake a consultation process in 2020 to determine which Schedule 4 medicines beyond diazepam and tramadol should be declared monitored medicines under the MPTG Act.

The ACT Government notes the Chief Coroner's recommendation in relation to Schedule 3 medicines, however, does not intend to pursue monitoring of Schedule 3 medicines at this stage due to the considerable regulatory burden this would place on health practitioners. The ACT Government considers that the health harms and scheduling status of Schedule 3 medicines are better considered by the Therapeutic Goods Administration.

c) in the alternative, that the ACT Health Minister consider widening the scope of monitored medicines under the DORA system to include certain prescription and over-the-counter medications that may have significant sedating or other adverse effects when taken in combination with opioids or benzodiazepines;

The ACT Government supports this recommendation and will undertake a consultation process in 2020 to determine which Schedule 4 medicines should be declared monitored medicines under the MPTG Act.

d) that the ACT Health Minister consider adding functionality to the DORA system to highlight where a patient has demonstrated drug-seeking behaviour, including but not limited to, when a patient has signed a medication contract; and

The ACT Government supports this recommendation. The DORA system already includes functionality to highlight to health practitioners where a drug dependent patient is approved to receive Opioid Maintenance Treatment or is known to be exhibiting drug-seeking behaviour.

DORA does not currently have functionality to display where a patient has signed a medication contract.

Additional alert functionality will be achieved through the ACT's adoption of the National RTPM system by June 2021. Options to display where a patient has a signed ACT medication contract will also be explored when developing ACT business requirements for the national system.

e) that the ACT Health Minister consider making access to and use of the DORA system mandatory for all ACT prescribing physicians and pharmacists prior to writing and/or dispensing prescriptions;

The ACT Government notes the Chief Coroner's recommendation that the use of the DORA system be made mandatory for prescribers and pharmacists. DORA was implemented under the MPTG Act as a voluntary system, modelled on the Tasmanian system which has been linked with a reduction in opioid related deaths. System limitations preclude the use of DORA as a mandatory system at this stage.

Further consideration of the proposal to mandate the health practitioner use of DORA will be deferred until such time as the ACT has adopted the national RTPM framework, and a regulatory impact assessment is undertaken in consultation with stakeholders.