QUESTION ON NOTICE

Question No. [number] of [Year]
House of Assembly Standing Committee on Government Administration B

ASKED BY: Ella Haddad MP

ANSWERED BY: Hon Roger Jaensch MP

QUESTION:

1. Regarding the comments provided by Mr Sam Halliday, Pharmaceutical Services Branch (PSB), at the hearing that PSB look to best practice research and clinical understanding to inform decision making, such as the AADPA Australian Evidence-Based Clinical Practice ADHD Guidelines, to what extend has that occurred? Are there any examples that can be referred to?

2. Noting that some of the recommendations of the AADPA Guidelines sit within other jurisdictions, what recommendations in the Guidelines are within the scope of the Tasmanian Government to consider and/or implement? If any, is there any interest in considering such recommendations?

3. What specific measures, if any, has the PSB implemented or considered to streamline the stimulant medication application and approval process to reduce delays that psychiatrists currently experience?

4. Can you describe how the PSB balances the risk of stimulant misuse against the clinical urgency for ADHD patients needing timely access to medication?

5. Is the PSB aware of the extent to which regulatory requirements exacerbate geographical barriers or workforce shortages,

particularly regarding access to ADHD-specialised psychiatrists in rural Tasmania?

6. What regulatory flexibility exists, or could be considered, to mitigate the challenges posed by lengthy waiting lists and limited availability of ADHD specialists?

7. How do current prescription regulations impact continuity of care for ADHD patients transitioning between psychiatrists or general practitioners?

8. Given a number of issues raised during the hearing appeared to be more likely an issue of misunderstanding or miscommunications between government, clinicians and/or patients, is there a need to review what information is available to ensure all stakeholders have the best possible understanding of the regulatory framework and how to best navigate it?

9. A request for a statistical breakdown on s59E applications assessed at Levels 1, 2, and 3 between 14 May 2024 and 14 November 2024 (see additional email from the Committee)

10. Does Forensic Mental Health Services have a role in decision making about which medications are available or permitted to people detained in Tasmanian Prison Service facilities? If so, what is their role?

ANSWER:

1. The Pharmaceutical Services Branch (PSB) applies evidence informed and risk-based approaches to the assessment of s59E authority to prescribe applications consistent with Quality Use of Medicines principles, current profession endorsed clinical guidelines, and scientific literature on benefits and harms of Schedule 8 medicines.

   The Guideline provided by AADPA is one example of various sources of information, including peer-reviewed published literature and advice from relevant specialist medical practitioners, used to inform decisions made by the Department of Health when assessing applications for authority to prescribe.

2. The Guidelines provide recommendations for clinicians to consider when caring for patients with ADHD. This includes diagnosis and therapeutic management guidance of ADHD. These clinical care decisions are for

individual health practitioners to make in the context of specific patient circumstances.

3. The Department of Health has experienced significant increase in activity required to continue administration of s59E of the Act and has a continual quality management focus on streamlining and improving this administration.

   The s59E authorisation approach for Schedule 8 psychostimulants for ADHD has deliberately evolved in recent years to improve efficiency and minimise delays with a move away from considering explicit doses, limiting age, and clinical review period limits.

   In April 2022 general practitioners were enabled to seek authorisation for the prescribing of Schedule 8 psychostimulants where an assessment and diagnosis of the patient has been conducted by a relevant medical specialist in the condition being treated.

   This administrative change allowed for greater flexibility in who could seek authorisation. This change served to better accommodate the increasing prevalence of interstate telehealth psychiatry services who routinely entrust prescribing functions to a patient's GP.

   In October 2022 the inaugural 'Australian Evidence-Based Clinical Practice Guideline for ADHD' was published by the Australasian ADHD Professionals Association (AADPA). This clinical practice guideline has further informed the approach taken to s59E authorisation, along with feedback from stakeholder groups, and advice provided by Department of Health specialist medical practitioners.

   In January 2024 the Department of Health published updated guidance for stakeholders on the regulatory process for psychostimulants 'Fact Sheet: Seeking Authorisation to Prescribe Schedule 8 Psychostimulants in Tasmania'. This was aimed to improve understanding of the regulatory process among prescribers and stakeholder groups.

   In May 2024 the Department of Health implemented an online authority application form as part of TasScript, Tasmania's implementation of the national real time prescription monitoring system. The step provided a streamlined way in which application for authorisation could be submitted and further supported prescribers to meet their obligations.

   To facilitate timely assessment of applications, resources have been re-directed from other regulatory functions to support execution of this delegation. The Department of Health has sought to reduce administrative burden through a stepwise increase in the standard duration of s59E authorities issued for psychostimulants.

   In July 2024 the standard duration an authority was issued on uncomplicated applications, was increased from 24 to 36 months, to reduce any regulatory burden from submitting applications.

4. In the regulation of access to Schedule 8 psychostimulants under s59E, PSB has continually adjusted and assessed risk appetite and tolerance to administer s59E functions to strike the right balance between access and public health protection.

   PSB strives to be a responsive regulator by applying evidence informed and risk-based approach to the assessment of s59E applications consistent with *Quality Use of Medicines* principles, current profession endorsed clinical guidelines, and scientific literature on benefits and harms of Schedule 8 medicines.

   This approach has included actively seeking and considering relevant stakeholder feedback, keeping abreast of changes to clinical guidance, participating in working groups locally and nationally and monitoring of trends, outcomes and emerging issues. This approach supports the PSB to have a strong understanding and support the environment it co-regulates.

   PSB has been involved in Tasmanian Health Service (THS) working groups led by THS Women's and Children's Services to support development of health system improvements to ADHD diagnosis and management for Tasmanian children.

   The Department of Health has been working collaboratively with Primary Health Tasmania (PHT) and other stakeholders, to educate and provide pathway assistance so that Tasmanians can access appropriate assessment and diagnostic services, and any treatments recommended by appropriately trained and experienced specialist medical practitioners. This has culminated in PHT developing Health Pathways for adult and child ADHD diagnosis and management, and PHT publication of FAQs to support optimal care in this setting.

   The s59E delegate assessment focuses on risk evaluation and mitigation strategies to support safe and effective care with Schedule 8 psychostimulants whilst minimising unintended harms from concurrent unsafe substance use or diversion of these medicines.

   This assessment approach can assist to:

   - Ensure that patients who may be at increased risk of preventable harm when prescribed Schedule 8 psychostimulants are appropriately identified, the risks and benefits in the individual have been carefully considered by the treating clinician, and that care is being provided with appropriate risk mitigation strategies and monitoring.

   - Minimise preventable harms to the public from diversion of prescribed Schedule 8 psychostimulants into the community for illicit purposes.

   - Ensure children receiving Schedule 8 psychostimulants are provided a supported framework to receive their prescribed

medicines, if risks in their care environment have been identified with respect to safekeeping of medicines.

The timeframe for delegate decision making on an application in clinically uncomplicated cases is usually one to two days.

Section 59E also allows for verbal authority to be provided to support urgent clinical care scenarios or swift transitions of care whilst a formal application is made.

This timeframe can be prolonged if one or a combination of the below occurs:

- The prescriber applying has not provided sufficient information with the application to enable an informed decision by the delegate and is requested to provide further information;
- The application assessment identifies increased risk of harm from Schedule 8 medicines or illicit substances which require risk evaluation and mitigation strategies to be considered by the prescriber applicant or specialist medical practitioner involved in the patient's care; and
- The application is clinically complex with the delegate seeking advice from a Consultant Medical Officer or a panel of medical practitioners with specialist qualifications.

5. The Department of Health is aware of clinical care challenges related to geographical barriers and workforce shortages across Australia. Decisions made by PSB on authorities to prescribe consider these issues.

6. The legislative safeguards applied at both a national and state level regarding Schedule 8 medicines such as psychostimulants for ADHD exist to support patient and community safety.

   As described in Question 3, the Department of Health continually looks at emerging evidence, published information, alternative models of care and works with stakeholders to enhance service delivery and access to support safe and evidence-based care.

   A review of the *Poisons Act 1971* is currently underway which will support improved access to medication whilst ensuring appropriate risk-based controls are in place to mitigate harm.

   As part of this, consultation recently concluded on proposed changes to the *Poisons Act 1971* to make it easier for Tasmanians, particularly those with ADHD, to access certain high-risk medicines legitimately prescribed by an appropriately qualified health professional interstate. If supported, these provisions will support improved access to prescribed psychostimulants for the treatment of ADHD.

7. The Department of Health's approach to authorising prescribers to make available Schedule 8 psychostimulants is based on the medical profession's expectation of minimum training standards that medical conditions which may benefit from treatment with Schedule 8 psychostimulants, should be assessed and diagnosed by an appropriately qualified specialist medical practitioner.

   For the treatment of ADHD with Schedule 8 psychostimulants this has traditionally required patient consultation with a psychiatrist or paediatrician.

   This approach is consistent with the medical profession's long-standing expectation that relevant specialist training and education (such as that provided in postgraduate medical training fellowships by the Royal Australian and New Zealand College of Psychiatrists and the Royal Australasian College of Physicians) is required to diagnose ADHD.

   The current Tasmanian regulations allow for a nominated medical practitioner, or their practice colleague, to be medico-legally responsible for prescribing Schedule 8 medicines. This is an important patient and practitioner safeguard to ensure medication errors and adverse effects are minimised.

   Section 59E also allows for verbal authority to be provided to support swift transitions of care whilst a formal application is made.

   This framework does not exist in isolation and operates alongside national regulations that impose rules on eligibility for subsidised medicines and product safety and quality standards

8. The Department of Health publishes information to support stakeholders understanding of the Tasmanian regulatory framework applying to the prescribing of Schedule 8 ADHD medicines. The Department of Health welcomes feedback on this existing material to ensure it supports the needs of the community.

9. The national real time prescription monitoring database used by the Department of Health for administering s59E authorisations does not enable reporting on this level of detail; however, it can be confirmed that where staged supply conditions are included as a safeguard on an authority to prescribe under s59E, the advice of either a Consultant Medical Officer (Level 2) or the Psychostimulant Advisory Committee (Level 3) will have been sought.

   This is to ensure the balance of benefit vs harm in higher-risk clinical scenarios, has had some sort of objective relevant medical specialist review.

   With reference to the statistics previously provided to the Committee, this would indicate that 7.77 per cent (n = 500) of approved authorities would have been through either Level 2 or 3 of the assessment process.

10. Services provided in prison by the THS, including those provided by the Forensic Mental Health Service (FMHS), are bound by the Tasmanian Medicine's Formulary. If a doctor wishes to prescribe a medication outside of the Formulary, approval must be sought from the Tasmanian Medicines Access and Advisory Committee (TMACC). The FMHS is in the same position as other THS services in that respect.

    The importance of strong working relationships between the Correctional Primary Health Service (CPHS), FMHS and services provided under the Tasmanian Prison Service (TPS), cannot be overstated. For matters impacting the prescribing of psychotropic medications in prison, including those used in the treatment of ADHD, the FMHS is a key stakeholder with subject matter expertise. In relation to ADHD prescribing, the FMHS and CPHS Specialty Directors are already engaged on this issue and have sought insights from interstate services with experience in the management of ADHD in the prison context.

Impact of lockdowns (question taken on notice):

The exact impact of lockdowns on Prison Mental Health Service (PMHS) clinical activity is difficult to quantify.

The FMHS is not in a position to provide specific data because the PMHS does not operate on a typical 'clinic based' model, where appointments are booked prospectively and where activity and failed appointments would be recorded on iPM. Rather the PMHS is a community-modelled service operating on a more flexible model which includes the ability for PMHS clinicians to mobilise into the prison facility to see patients (rather than purely clinic based). This is arguably better suited to the fluid nature of mental health clinical work in prison. PMHS activity under this model is captured post-event.

While lockdowns do impact PMHS access to consumers, the PMHS has a strong working relationship with the TPS and efforts are typically made to facilitate assessments despite lockdowns, especially of acutely unwell prisoners. Non-urgent reviews impacted by lockdowns would ordinarily be rescheduled within the PMHS workflow.

APPROVED/NOT APPROVED

Hon Roger Jaensch MP
Minister for Mental Health and Wellbeing

Date: 10/6/25