Pharmaceutical Services Branch

Fact Sheet: Seeking Authorisation to Prescribe Schedule 8 Psychostimulants in Tasmania

There are currently three Schedule 8 psychostimulants (dexamfetamine, methylphenidate and lisdexamfetamine) registered for use in Australia by the Therapeutic Goods Administration (TGA). Indications for use differ for each substance and include attention-deficit hyperactivity disorder (ADHD), binge-eating disorder, narcolepsy and other hypersomnias.

The Department of Health administers the Tasmanian *Poisons Act 1971* and *Poisons Regulations 2018*. Under regulation 24 of the *Poisons Regulations 2018* a medical practitioner is required to seek and obtain an authority from the Secretary of the Department of Health prior to issuing a prescription for a Schedule 8 psychostimulant for a patient. These authorities are issued pursuant to section 59E of the *Poisons Act 1971*. A medical practitioner must be present and practicing in Tasmania to be authorised to prescribe Schedule 8 psychostimulants in Tasmania.

The purpose of this fact sheet is to outline the framework for prescribers to gain authorisation under section 59E of the *Poisons Act 1971* to prescribe Schedule 8 psychostimulants in Tasmania.

This fact sheet does not include information on funding of medicines under the Australian Government's Pharmaceutical Benefits Scheme (PBS) and is not a clinical resource with respect to diagnosis and management of health conditions.

Diagnosis and Treatment Recommendations

Medical conditions which may benefit from treatment with Schedule 8 psychostimulants should be diagnosed by an appropriately qualified specialist medical practitioner. This includes psychiatrists, paediatricians, sleep physicians and neurologists. Assessment and diagnosis of medical conditions should occur using accepted diagnostic criteria and management approaches considered based on profession endorsed clinical guidelines and evidence-based resources.

Prescribers Eligible for Authorisation:

Section 59E applications will be accepted from appropriately qualified specialist medical practitioners practicing in Tasmania including psychiatrists, paediatricians, sleep physicians and neurologists.

Additionally Tasmanian general practitioners may apply to be authorised to prescribe Schedule 8 psychostimulants where an assessment and diagnosis of the patient has been conducted by a relevant medical specialist in the condition being treated. Such applications should be accompanied by a comprehensive clinical report from the relevant medical specialist including diagnosis, management plan, and recommended treatment regimen.

The authorisation of medical practitioners under section 59E to prescribe Schedule 8 medicines is restricted to medical practitioners physically present and practicing medicine in Tasmania. An interstate medical practitioner (e.g., practicing telehealth interstate) cannot be authorised under section 59E. However, an appropriately qualified medical specialist interstate can support a Tasmanian located general practitioner to make an application under section 59E.

General Process for Section 59E Application and Authorisation:

An application for authority to prescribe Schedule 8 psychostimulants under Section 59E can be made using the form *'Application for authorisation to prescribe Schedule 8 medicines under section 59E of the Poisons Act 1971'* and can be submitted via email to pharmserv@health.tas.gov.au

Applications are then assessed by a pharmacist within the Department's Pharmaceutical Services Branch (PSB) who is a delegate for the Secretary for purposes of section 59E. On assessment the delegate may decide to refuse the application, issue an authority, or issue an authority with conditions. Applications which do not include sufficient detail to allow an informed decision to be made by the delegate will not be assessed and will be referred to the applicant for further specific information. In some cases, the delegate may request further information to inform the assessment which could include the results of a urine drug screen, sleep study results, or occasionally a second supporting opinion from a specialist medical practitioner.

Authorities will generally be issued for a maximum of 24 months but may be issued for a shorter duration at the delegate's discretion. Paediatricians making an application for a child may be issued an authorisation until the child turns 18 years old.

Subsequent applications from a general practitioner to renew an expired authorisation should be accompanied by documentation indicating the patient has continued to engage in clinical review with a relevant medical specialist (at intervals as defined by the relevant medical specialist) with the patient's current drug and dose regimen remaining appropriate.

A section 59E authority issued covers the named medical practitioner and any medical practitioner that works within the same medical practice.

Exceptional or Urgent Circumstances:

In urgent or exceptional circumstances, a Tasmanian medical practitioner can telephone Pharmaceutical Services Branch and seek verbal authorisation under section 59E for short-term prescribing arrangements. In urgent and exceptional circumstances, the section 59E delegate still requires the medical practitioner to have undertaken appropriate clinical due diligence. Examples may include:

- Where the patient is a subject of a section 59E authorisation for Schedule 8 psychostimulants, but a different non-authorised medical practitioner wishes to prescribe the Schedule 8 psychostimulant due to exceptional circumstances (e.g., transfer in treating medical practitioner, unable to secure necessary specialist medical appointment).
- Where the patient is treated with Schedule 8 psychostimulants interstate and during travel to Tasmania has insufficient dispensed medicine remaining.
- Where the patient is a subject of a section 59E authorisation for Schedule 8 psychostimulants, but there is an urgent need to vary the authorised regimen (e.g., when the usual medicine is unavailable due to stock shortages).

Regimen and Dosage:

It is expected that in most cases the treatment of patients with Schedule 8 psychostimulants will be at doses within the TGA approved Product Information (PI) and profession endorsed clinical guidelines. Applications for doses exceeding those in the TGA approved PI should be accompanied by a detailed clinical rationale for the higher dose from the relevant medical specialist.
Authorities issued include specific psychostimulant(s) and maximum dosage, based on the requested regimen in the application. It is acknowledged that for some patients the prescriber may be titrating and adjusting psychostimulant treatment based on response, weight, or suitability. In clinical situations where the applicant believes it appropriate, after noting the clinical intention they may wish to include on their application:

- Multiple psychostimulant substances
- Multiple formulations of the same psychostimulant substance (i.e., immediate release and modified release)
- A maximum dose for upward titration

Patient Age:

Prescribers should be familiar with current TGA approved PI regarding the use of methylphenidate, lisdexamfetamine, and dexamfetamine at different ages. It is expected that in most cases the treatment of patients with Schedule 8 psychostimulants will be within the age parameters of TGA approved PI and profession endorsed clinical guidelines. Applications for a patient not within the TGA PI range for a Schedule 8 psychostimulant should be accompanied by a detailed clinical rationale from the relevant specialist medical practitioner.

Non-TGA Registered Indications:

Applications for authorisation to prescribe Schedule 8 psychostimulants for indications not registered by the TGA should be accompanied by a detailed clinical report from the relevant specialist medical practitioner outlining the rationale for use, recommended management plan, and account of other treatment options trialled.

Risk Evaluation and Mitigation Strategies (REMS):

The s59E application assessment process includes consideration of Risk Evaluation and Mitigation Strategies (REMS). A REMS 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, 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 where risks in their care environment with respect to safekeeping of medicines have been identified.

Prior to making an application or recommendation for treatment with a Schedule 8 psychostimulant, it is expected that medical practitioners undertake a comprehensive clinical and psychosocial assessment to inform their management plan. This should include taking a comprehensive history of past or present illicit substance use and history of unsafe alcohol or substance use. The management plan should include an overall patient risk-benefit assessment for treatment and where appropriate detailed risk mitigation and monitoring strategies to support safe patient care.

Complex Applications:

For applications where complex clinical issues are involved, a delegate may choose to seek advice from a Consultant Medical Officer (CMO) or a panel of two or more relevant specialist medical practitioners. Applications requiring CMO or panel advice comprise a very small percentage of all Schedule 8 psychostimulant applications. The CMO or panel will be experienced clinician(s) with appropriate background and training in the areas of paediatrics, addiction medicine or psychiatry. After seeking advice, the decision on the application remains with the delegate.

Review of a Decision:

Formal review arrangements exist for authorities for Schedule 8 psychostimulants issued under section 59E. Where a delegate has included conditions on an authority or has refused to issue an authority, a medical practitioner, a patient, or their carer, may make application to request a review of the decision. Grounds for review may be clinical in nature or relate to other facts relevant to the application. A review is undertaken by a delegate not involved in the original decision. Information on this process and application form is available on the Department's website.

Where can I find more information?

For further enquiries please contact Pharmaceutical Services Branch, Department of Health via:

Telephone: (03) 6166 0400
Email: pharmserv@health.tas.gov.au