TG181/12

NSW PHARMACEUTICAL REGULATORY GUIDELINES

CRITERIA FOR THE MANAGEMENT OF MEDICATION FOR ATTENTION DEFICIT HYPERACTIVITY DISORDER IN CHILDREN AND ADOLESCENTS

The management (prescribing and supplying) of dexamfetamine, methylphenidate and lisdexamfetamine (central nervous psychostimulants) is subject to compliance with the *Poisons and Therapeutic Goods Act 1966*, and its regulations.

Prescribing and supplying of psychostimulants requires prior authorisation by the NSW Ministry of Health.

ABOUT THIS GUIDELINE

This document replaces TG181/10 *Criteria for the Diagnosis and Management of Attention Deficit Hyperactivity Disorder in Children and Adolescents.* This document is to inform Paediatricians, Psychiatrists, Child & Adolescent Psychiatrists, Neurologists, Other Designated Prescribers (ODPs) and General Practitioners about the criteria for obtaining authorisation to prescribe or supply psychostimulants for Attention Deficit Hyperactivity Disorder (ADHD).

'Children and adolescents' refers to persons *under* the age of 18 years. Separate guidelines have been developed for the management of ADHD in adults (see TG190 *Criteria for the Management of Medication for Attention Deficit Hyperactivity Disorder in Adults*).

The document is set out in the sections described below:

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SECTION 1: PRESCRIBER ELIGIBILITY

The assessment of ADHD in children and adolescents and initial prescribing of psychostimulants is generally limited to Paediatricians, Psychiatrists, Child & Adolescent Psychiatrists and Neurologists.

As a minimum, the DSM-5 diagnostic criteria should be met for a diagnosis of ADHD to occur.

The following prescribers may apply for an authority:

1.1 Paediatricians, Child & Adolescent Psychiatrists, Psychiatrists, and Neurologists

The following specialists generally manage ADHD in children and adolescents:

- **Paediatricians** who are members (or eligible for membership) of the Paediatrics and Child Health Division, Royal Australian College of Physicians (RACP).
- **Child & Adolescent Psychiatrists** who are members (or eligible for membership) of the Royal Australian & New Zealand College of Psychiatrists (RANZCP) or Faculty of Child and Adolescent Psychiatry, Royal Australian & New Zealand College of Psychiatrists (RANZCP).
- **Psychiatrists** (when prescribing for **16-17 years old**) who are members (or eligible for membership) of the Royal Australian & New Zealand College of Psychiatrists (RANZCP)
- **Neurologists** (when prescribing for **16-17 years old**) who are members (or eligible for membership) of the Royal Australian & New Zealand College of Physicians (RACP)

Paediatricians and Child & Adolescent Psychiatrists may apply to the NSW Ministry of Health for a **General Authority** number (CNS Number) to prescribe psychostimulants for patients, without the need for an individual application, provided that:

a. Patient management is in accordance with the criteria listed in this document, Product Information (PI) and published recommendations from the RANZCP and RACP with regard to psychostimulants, as outlined in Section 7, **and**
b. The prescribing is in accordance with the **routine prescribing criteria** (Section 3).

In cases where the criteria are not met or where any of the exclusions apply, an application for authority to prescribe for an individual patient must be made.

An application form for a general authority to prescribe psychostimulants can be obtained at:
Application for General Authority to Prescribe Psychostimulants for ADHD

1.2 Other Designated Prescribers (ODPs)

An **Other Designated Prescriber** (ODP) *must have* an approval to prescribe psychostimulants. To obtain an approval, an application can be made by sending a full resumé including a rationale for the application to the NSW Ministry of Health **Stimulants Subcommittee**, a subcommittee of the Medical Committee, established under Section 30 of the *Poisons and Therapeutic Goods Act 1966.* Applications should

be sent only by email to MOH-PharmaceuticalServices@health.nsw.gov.au with the subject: ODP Request for Stimulants Subcommittee.

Generally, ODPs are:

- Psychiatrists and Neurologists, if prescribing for a child or adolescent aged between 4 and 15 years
- Advanced trainees in community paediatrics or child psychiatry
- General Practitioners, with paediatric training, working in rural or remote areas
- General Practitioners in a predominantly paediatrically orientated practice

ODPs must obtain an authority for each individual patient (see 'Individual Patient Applications' in Section 4). Applications which fall outside the **Routine Prescribing Criteria** (see Section 2) will not be approved. These patients should be referred to a Paediatrician or Child & Adolescent Psychiatrist.

1.3 General Practitioners

General Practitioners who have not been approved as an ODP may apply for individual patient authorisation to prescribe a psychostimulant for a person aged under 18 years. General Practitioners seeking such authorisation must obtain written support from the patient's current treating specialist supporting the shared care arrangements. The support should specify the drug, dose and care arrangements.

General Practitioners will not be issued with a CNS authority number

Applications from General Practitioners to increase the dose or change the drug must be supported by the patient's current treating specialist.

SECTION 2: ROUTINE PRESCRIBING CRITERIA

All of the following **Routine Prescribing Criteria** must be met. In cases where these criteria are not met or where any of the following exclusions apply, an application for authority to prescribe for an individual patient must be made (see Section 3).

2.1 Age Limits

- For prescribing of dexamfetamine and methylphenidate patients must be aged **4** to **17** years (inclusive).
- For prescribing of lisdexamfetamine patients must be aged **6** to **17** years (inclusive).

2.2 Dosage

Prescribed doses must not exceed:

- **1mg/kg/day** for **dexamfetamine**, up to a maximum of **50mg per day**
- **2mg/kg/day** for **methylphenidate**, up to a maximum of **108mg per day**
- a maximum of **70mg lisdexamfetamine** per day

The maximum dose, for each of the drugs specified above, represents a ratio of 1. If multiple psychostimulants are being prescribed, the sum of ratios must not exceed 1.

For example:

- Dexamfetamine 25mg (25mg/50mg = 0.5; **ratio = 0.5**) + methylphenidate 54mg (54mg/108mg = 0.5; **ratio = 0.5**);
  therefore 0.5 + 0.5 = 1.0 – **within routine criteria**

- Dexamfetamine 30mg (**ratio = 0.6**) + methylphenidate 54mg (**ratio = 0.5**); therefore 0.6 + 0.5 = 1.1 – **requires individual authority and written support from an independent specialist**
- Dexamfetamine 50mg (**ratio = 1.0**) + methylphenidate 54mg (**ratio = 0.5**); therefore 1.0 + 0.5 = 1.5 – **requires individual authority and written support from an independent specialist**

2.3 Exclusionary factors

Routine prescribing is not available for patients if:

- the age is under 4 years when prescribed methylphenidate or dexamfetamine, or the age is under 6 years when prescribed lisdexamfetamine,
- the dosage is higher than the range specified Section 2.2
- the DSM-5 criteria for ADHD are not fulfilled

Paediatricians and Child and Adolescent Psychiatrists must make individual patient applications for patients outside the routine prescribing criteria (see Sections 3 and 4). General Authority numbers cannot be used.

SECTION 3: APPLICATION FOR AUTHORITY TO PRESCRIBE FOR CASES OUTSIDE THE ROUTINE PRESCRIBING CRITERIA

Paediatricians and Child and Adolescent Psychiatrists must make individual patient applications if the prescribing is outside the routine prescribing criteria. Specific application requirements must be met for children aged two and three.

3.1 Children under two years of age

Authority to prescribe will not be granted.

3.2 Children aged two

Before the initiation of psychostimulant therapy, an individual application accompanied by a second opinion and a detailed report must be forwarded to the Ministry of Health, for consideration by the Stimulants Subcommittee.

The Stimulants Subcommittee is a subcommittee of the Medical Committee, established under Section 30 of the *Poisons and Therapeutic Goods Act 1966* to advise the Ministry of Health on the issuing of authorities to prescribe drugs of addiction. The Stimulants Subcommittee specifically considers applications for authority to prescribe Schedule 8 psychostimulants for the treatment of ADHD in children and adolescents.

A detailed report must include:

a. Description of the behaviour in at least two settings, as described by day care providers, allied health therapists, parents, or schoolteachers.
b. Assessment of functional impairment, for example ability to meet age-appropriate behavioural expectations, quality of peer or sibling interactions and achievement in relation to ability.
c. Response to non-pharmacological intervention. Three months is the maximum length of authority for children aged two.

Within three months, the original prescriber, **and** the specialist giving the second opinion, must provide reports indicating that psychostimulant therapy is appropriate.

Applications for authority **renewals** for children **aged two** must be accompanied by a report from the initial prescriber **and** from the specialist giving the second opinion, **until age three**.

Second opinions must come from an independent practitioner experienced in the treatment of ADHD. Reports from other observers (e. g. parents, caregivers, teachers) on medication effects are essential with subsequent applications.

3.3 Children aged three

A generally authorised prescriber may initiate a trial of dexamfetamine and/or methylphenidate using their CNS number. A detailed report (as outlined for children aged two) must be forwarded within three months of the onset of the trial so that authorisation of further prescription can be considered by the Stimulants Subcommittee.

A Paediatrician or Child and Adolescent Psychiatrist who does not possess a general authority number may apply for an individual patient authority to initiate a trial of dexamfetamine and/or methylphenidate provided a second supporting opinion from an independent specialist has been obtained.

3.4 Higher dosage for children within the acceptable age limit

For children who satisfy the age limit within the routine prescribing criteria, a dose higher than the routine prescribing criteria dose may be trialed by Paediatricians and Child & Adolescent psychiatrists.

An individual **high dose** patient application must be submitted **within one month** of commencing the trial. These applications will be referred to the Stimulant Subcommittee (SSC). Supporting documentation will be required as follows:

- **current report** including the reasons for not using the alternate psychostimulant medication within the criteria (e.g., if applying for dexamfetamine, reasons must be provided as to why a dose of methylphenidate of 2mg/kg/day or less is not being used),
- **growth charts** or height/weight percentiles for the period from the commencement of psychostimulant treatment to the present (NOTE: where available, growth details obtained prior to the commencement of treatment should be provided), and
- **reports from relevant observers** (e.g., parents, teachers) documenting the advantages of using a dose higher than that specified in the routine prescribing criteria.

The following application form must be used to obtain approval to prescribe a dose higher than that specified in the routine prescribing criteria:

Application for Authority to Prescribe or Supply a Schedule 8 Drug - Psychostimulant for ADHD

SECTION 4: INDIVIDUAL PATIENT APPLICATIONS

Authorisation for **ODPs** to prescribe psychostimulants can only be granted following individual patient application. All applications must fall within the routine prescribing criteria (See Section 2).

Authorisation for Other Designated Prescribers to prescribe psychostimulants can only be granted following individual patient application. All applications must fall within the routine prescribing criteria. Individual patient applications by generally authorised

prescribers (Paediatricians and Child Psychiatrists) for cases which fall outside the routine prescribing criteria, need to be accompanied by a thorough clinical report. The report, as appropriate, should outline the clinical history, the patient's height and weight (with measurements plotted on CDC Growth Charts), the differential diagnoses, assessments made or planned, the presence or absence of co-morbid conditions, the family circumstances, and all other treatments instituted or planned.
Such applications will be referred to the Stimulants Subcommittee. An interim authority may be granted pending subsequent consideration by the Subcommittee.

The Stimulants Subcommittee can request additional reports and/or other opinions on any patient within or outside routine criteria.

If substance abuse is current, the application or second opinion should be from an addiction medicine specialist or an addiction psychiatrist.

Concerns about, or evidence of, the misuse of appropriately prescribed psychostimulant medication should be discussed with the patient or the patient's carer and appropriate measures should be taken to address the misuse. Applicants are advised to consider if the patient would benefit from a review by an addiction medicine specialist or an addiction psychiatrist to manage any perceived drug dependence issues.

An application form for an individual patient authority can be obtained at:

Application for Authority to Prescribe or Supply a Schedule 8 Drug - Psychostimulant for ADHD

SECTION 5: TREATMENT OF OLDER ADOLESCENTS AND YOUNG ADULTS (16 TO 17 YEARS)

5.1 Psychiatrists

Psychiatrists may initiate treatment in patients who are aged 16 to 17 years (inclusive).

5.2 Neurologists

Neurologists may initiate treatment in patients who are aged 16 to 17 years (inclusive).

5.3 Paediatricians

Treatment cannot be initiated by a Paediatrician in a patient who is 18 years of age or older.

A Paediatrician who has diagnosed and treated a patient for ADHD prior to age 18 may, in extenuating circumstances including an ongoing therapeutic relationship, continue treatment with psychostimulants until age 25. Prescribing for persons aged 18 years or over must be in accordance with the latest version of TG190 *Criteria for the Management of Medication for Attention Deficit Hyperactivity Disorder in Adults* available at:

Criteria for the Management of Medication for ADHD in Adults

Provided that management is in accordance with the criteria and conditions outlined in TG190, prescriptions must be endorsed with a Paediatrician's CNS number.

Under TG190, the maximum daily dose that may be prescribed to a person age18 years or over without an individual patient authority is:

- 30mg dexamphetamine, or

- 60mg methylphenidate daily in immediate release (IR), or
- 80mg methylphenidate in controlled release (CR) formulations, or
- 70mg lisdexamfetamine.

The maximum dose, specified above, represents a ratio of 1.

If multiple psychostimulants are being prescribed, the sum of ratios must not exceed 1.

For example:

- Dexamfetamine 15mg (ratio = 0.5) + methylphenidate (IR) 30mg (ratio = 0.5) = 1.0 – **within routine criteria**
- Dexamfetamine 20mg (ratio =0.6) + methylphenidate (CR) 40mg (ratio = 0.5) = 1.1 – **requires individual authority and written support from an independent specialist**
- Dexamfetamine 30mg (ratio =1.0) + methylphenidate (CR) 40mg (ratio = 0.5) = 1.5 – **requires individual authority and written support from an independent specialist**

Therefore, where a patient is continuing a dose higher than that specified in TG190, an application for approval to continue prescribing should be submitted as soon as practicable after the patient turns 18 years of age, unless a valid authority already exists.

An application form to prescribe psychostimulants for a patient aged 18 year or over (as required under TG190) can be obtained at:

Application for Authority to Prescribe or Supply a Schedule 8 Drug - Psychostimulant for ADHD

By age 25 years the patient must be referred to a Psychiatrist or Neurologist if further psychostimulant prescribing is required.

SECTION 6: PRESCRIPTIONS FOR PSYCHOSTIMULANTS

All prescriptions for dexamfetamine, lisdexamfetamine and methylphenidate must be endorsed, with either the prescriber's **general authority number** (**CNS** …….) or the authority number (**AU** .....) where an individual authority has been obtained.

In accordance with clause 90 of the *Poisons and Therapeutic Goods Regulation 2008*, a pharmacist must **not** dispense or supply a psychostimulant (dexamfetamine, lisdexamfetamine or methylphenidate) unless the prescription is endorsed with one of these numbers.

> **NOTE: These requirements apply to all prescriptions for psychostimulants irrespective of whether they are listed on the Pharmaceutical Benefits Scheme (PBS) or if they are non-PBS (private) prescriptions.**

Prescriptions for Schedule 8 drugs are only valid for 6 months and must specify repeat intervals if repeats are ordered. Prescriptions may be issued for a shorter period than 6 months if considered appropriate. Further information about prescribing Schedule 8 drugs can be found in TG12 *Guide to the Poisons and Therapeutic Goods Legislation for Medical, Nurse and Midwife Practitioners and Dentists* available at:

Guide to the PTG legislation for Medical Practitioners

All Schedule 8 medicines are generally associated with a higher risk of misuse and diversion. Prescriptions should be issued in quantities and at intervals consistent with the intended use.

Further information including processing times, FAQs and appeal mechanisms is available from the Pharmaceutical Services website:

Pharmaceutical Services

NOTE: Failure to use the correct application form or to complete it may delay the processing of the application.

SECTION 7: CONTRAINDICATIONS, PRECAUTIONS AND OTHER CONSIDERATIONS

The Ministry of Health recommends that all prescribing is in accordance with the approved **Product Information** (PI) and with published recommendations from the **RANZCP** and **RACP** with regard to psychostimulants. Further information may be found as follows:

- The Royal Australian College of Physicians Australia (RACP) publishes Guidelines on ADHD: Royal Australian College of Physicians
- The Royal Australian & New Zealand College of Psychiatrists (RANZCP) refers its members to the Canadian ADHD Practice Guidelines and the National Institute for Health and Clinical Excellence (NICE) Clinical Guideline 72 *Diagnosis and management of ADHD in children, young people and adults*: Royal Australian and New Zealand College of Psychiatrists

NOTE: Although co-morbidity may exist, ADHD should be the most prominent disorder.

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SECTION 8: SAFESCRIPT NSW (REAL TIME PRESCRIPTION MONITORING)

The NSW Ministry of Health recommends the use of SafeScript NSW to assist practitioners to make informed clinical decisions. SafeScript NSW should be checked for evidence of alerts or other issues related to the prescribing or supply of high-risk monitored medicines.

For links to registration and information about SafeScript NSW, visit SafeScript NSW.

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