



## Stimulant Prescribing Code Explanatory Notes August 2011

A reference to a **stimulant medicine** in these Notes means dexamphetamine and methylphenidate in any form.

A reference to an **authorised practitioner** in these Notes means a medical practitioner who holds a valid Stimulant Prescriber Number (SPN) issued by the Chief Executive Officer (CEO) of Health.

### 1. Overview

The regulatory control framework for stimulants requires prescribers initiating treatment with a stimulant to register with the Department of Health (DOH) and obtain a Stimulant Prescriber Number. **Authorised practitioners** can initiate treatment for patients who meet the criteria set out in the Stimulant Prescribing Code (the Code) by forwarding a completed *Notification of Treatment Using Stimulant Medication* form to the DOH. Where a patient does not meet the criteria set out in the Code an authorisation from the CEO of Health is required before treatment can be initiated.

### 2. Authorisation of Prescribers

2.1. An **authorised practitioner** must apply to the Department of Health and obtain a unique Stimulant Prescriber Number (SPN) prior to initiating treatment with a **stimulant medicine**.

2.2. To apply for an SPN, an **authorised practitioner** must be a practitioner registered with the Australian Health Practitioner Regulation Agency (AHPRA) whose principal place of practice is in Western Australia (WA), and be recognised as having specialist qualifications as a paediatrician, paediatric neurologist, neurologist, respiratory and sleep physician, thoracic medicine physician, rehabilitation physician, psychiatrist, child and adolescent psychiatrist or a specialist as determined by the CEO of Health.

2.3. A completed *Application to Obtain a Stimulant Prescriber Number* form is to be forwarded to the DOH.

2.4. **Authorised practitioners** applying for an SPN will be required to be familiar with, and comply with, the Stimulant Prescribing Code and agree to participate in a clinical audit of patients at a later date. Any future audit will be based upon research principles including the requirement for informed patient consent to access medical information.

### 3. Notification Forms

3.1. A *Notification of Treatment Using Stimulant Medication* form should be used for patients who meet the criteria set out in the Code (see section 5 for patients who do not meet the criteria).

- 3.2. An **authorised practitioner** is required to complete a *Notification of Treatment Using Stimulant Medication* form for **each** patient for whom they wish to initiate stimulant treatment.
- 3.3. A *Notification of Treatment Using Stimulant Medication* form is to be forwarded to the DOH at the same time as the first prescription for a patient is written.
- 3.4. A re- Notification of Treatment Using Stimulant Medication form is required to be completed when there is a change in:
- dose, when the quantity of drug required for the new dose will result in an additional standard pack to be supplied per month;
  - drug;
  - drug form (i.e. long acting or short acting);
  - nominated co-prescriber (the nomination as a co-prescriber relates both to the co-prescriber and the practice at which he/she is working. If the co-prescriber changes practice location, the co-prescribing arrangements need to be amended);
  - authorised practitioner;
  - patient details.
- 3.5. The authorised practitioner should provide a copy of the *Notification of Treatment Using Stimulant Medication* form to the nominated co-prescriber so that they are aware of the patient's current treatment regime.
- 3.6. A co-prescriber is not permitted to change a patient's treatment: only the **authorised practitioner** may do this.
- 3.7. The authorised practitioner is required to complete a *Notification of Stimulant Induced Psychosis* form for each patient on each occasion for whom they have made a definitive diagnosis of stimulant induced psychosis.
- 3.8. A *Notification of Stimulant Induced Psychosis* form is to be forwarded to the DOH within 72 hours of making the diagnosis.

#### 4. Criteria for the Prescribing of a Stimulant

The clinical criteria for the prescribing of stimulant medicines in WA are set out in the Stimulant Prescribing Code.

##### 4.1 Diagnosis

Patients must be diagnosed as having ADHD, brain damage, narcolepsy or depression.

4.1.1 Treatment of ADHD with stimulants may only be initiated by a neurologist, paediatric neurologist, paediatrician, psychiatrist, a child and adolescent psychiatrist or an authorised practitioner, whose principal place of practice is in WA, approved by the CEO. Patients are required to meet the ICD-10 or DSM-IV\_criteria.

4.1.2 Treatment of brain damage with stimulants may only be initiated by a neurologist, paediatric neurologist, rehabilitation physician or an authorised practitioner, whose principal place of practice is in WA, approved by the CEO.

- 4.1.3 Treatment of narcolepsy with stimulants may only be initiated by a paediatric neurologist, neurologist, respiratory and sleep physician, thoracic medicine physician or an authorised practitioner, whose principal place of practice is in WA, approved by the CEO.
- 4.1.4 Treatment of depression with stimulants may only be initiated by a psychiatrist, a child and adolescent psychiatrist or an authorised practitioner, whose principal place of practice is in WA, approved by the CEO.

## 4.2 Drug Screening

A urine drug screen should be undertaken by all patients 13 years and older before treatment with a stimulant is initiated. Further testing is recommended annually or as clinically appropriate.

## 4.3 Additional Requirements

### 4.3.1 Dose

All patients must be started on a low dose that is titrated according to the patient's response.

**In patients under the age of 18 years**, doses are not to exceed 1mg/kg/day for dexamphetamine up to a maximum of 60mg per day; or not to exceed 2mg/kg/day for methylphenidate up to a maximum of 120mg per day.

**In patients over the age of 18 years**, the dose of dexamphetamine is not to exceed 60mg per day, and the dose of methylphenidate is not to exceed 120mg per day when each drug is being used alone. *It is considered good practice to use lower doses in adults of low body weight.*

***Where both dexamphetamine and methylphenidate are being used together:***

**In patients under the age of 18 years**, doses should be converted to the equivalent amount of dexamphetamine. For methylphenidate, this is achieved by dividing the dose, in milligrams, by two and adding to the dexamphetamine dose, in milligrams. When the dose has been converted to this dexamphetamine equivalent amount, it must not exceed 1mg/kg/day of dexamphetamine to a maximum of 60mg daily.

E.g. If a 30kg child is prescribed 10mg dexamphetamine and 20mg methylphenidate, this should be converted to a total dexamphetamine equivalence of 10mg + 10mg = 20mg dexamphetamine equivalent daily.

**In patients over the age of 18 years**, there is a combined maximum of 12 tablets per day.

*It is considered good practice to use lower doses of each drug when the combination approach is being employed.*

For **long acting methylphenidate** (Ritalin LA<sup>®</sup> and Concerta<sup>®</sup>) the equivalent number of immediate release methylphenidate tablets should be used in the calculation to determine the maximum of 12 tablets daily.

Example 1: If a patient is prescribed one capsule of Ritalin LA<sup>®</sup> 40mg, the equivalent amount of four 10 mg tablets (40mg) of methylphenidate immediate release should be used in the calculation.

Example 2: If a patient is prescribed one capsule of 18mg of Concerta<sup>®</sup>, this should be *rounded* to two 10mg tablets (20mg) of methylphenidate immediate release tablets. 36mg of Concerta<sup>®</sup> should be rounded to 40mg, 54mg rounded to 50mg and so on.

The maximum dosage of 2mg/kg/day of methylphenidate up to a maximum of 120mg remain unchanged with the new formulations.

#### 4.3.2 Age

Treatment with a stimulant in children below 2 years of age will not be authorised.

Treatment with a stimulant in children between 2 and 4 years by an **authorised practitioner** in accordance with section 4.1 will require prior authorisation from the CEO (see section 5).

Treatment with a stimulant may be initiated in children between 4 years and 19 years by an **authorised practitioner** specialising in children in accordance with section 4.1.

Treatment with a stimulant may be continued in patients between 19 and 25 years by an **authorised practitioner** specialising in children, in accordance with section 4.1, if that patient had been treated with a stimulant by an **authorised practitioner** specialising in children since before they reached 19 years of age.

Treatment with a **stimulant medicine** may be initiated by an **authorised practitioner** specialising in adults in accordance with section 4.1, in patients aged 17 years or older.

#### 4.3.3 Co-morbidity

Treatment with a stimulant may not be initiated in patients with a history of psychosis, bipolar disorder, sustained significant substance abuse or diversion or misuse of Schedule 8 medicines within the previous 5 years, without prior authorisation from the CEO.

If an **authorised practitioner** becomes aware of a patient's history of psychosis, bipolar disorder, sustained significant substance abuse or diversion or misuse of Schedule 8 medicines within the previous 5 years, the patient's stimulant treatment is to be ceased. If the **authorised practitioner**

wishes to continue to treat the patient, an application for authorisation to treat the patient outside the criteria set out in the Code must be made.

#### 4.3.4 Frequency of Review

An **authorised practitioner** should ensure that all patients are reviewed on at least an **annual basis** for the continuation of appropriate stimulant treatment.

### 5. Application for Authorisation to Prescribe a Stimulant

- 5.1. An application to prescribe stimulants where a patient does not meet the criteria set out in the Code, is to be forwarded to the CEO by an authorised practitioner and may be considered by the Stimulants Assessment Panel. The application must be accompanied by a detailed report and information according to the relevant checklist. A completed *Notification of Treatment Using Stimulant Medication* form is also required.
- 5.2. The prescription for stimulants for an unapproved indication (see 4.1) requires a comprehensive report to be forwarded to the CEO by an **authorised practitioner**. The comprehensive report should be supported by evidence based literature for treating the condition proposed with stimulants.
- 5.3. To prescribe stimulants for clinical research, an application will require submission of a copy of the research proposal with approval from an Ethics Committee constituted in accordance with the Guidelines issued by the National and Medical Research Council (NHMRC). If applicable, a comprehensive report for each patient should be submitted.
- 5.4. Treatment of a patient with stimulants outside the criteria set out in the Code **cannot** be commenced until the authorised practitioner has received written authorisation from the CEO.
- 5.5. Where an authorisation is granted, only an **authorised practitioner** for the patient will be permitted. A co-prescriber will not be authorised other than in exceptional circumstances.

### 6. General Regulatory Matters

- 6.1. The CEO may revoke an authorisation or cancel a *Notification of Treatment Using Stimulant Medication* form forwarded to the DOH.
- 6.2. An **authorised practitioner** who has completed a *Notification of Treatment Using Stimulant Medication* form or has received a written authorisation from the CEO may request in writing that their *Notification of Treatment Using Stimulant Medication* or authorisation be cancelled.
- 6.3. Registrars are required to have prescriptions for stimulants countersigned by their supervising consultant except where the registrar has been endorsed as a co-prescriber in the *Notification of Treatment Using Stimulant Medication* form by the **authorised practitioner**.
- 6.4. **Authorised practitioners** should notify the CEO in writing if replacement prescriptions are required for lost, stolen or otherwise inaccessible medication.

- 6.5. Pharmacists are required to be familiar with the prescriber's handwriting or verify with the medical practitioner that the prescription is valid. Repeat prescriptions must be retained at the pharmacy.
- 6.6. **Authorised practitioners** are required to **specify intervals** between prescription repeats when writing prescriptions for stimulants. Prescriptions are valid for six months from the date they are written.

## 7. Authorised Practitioners on Leave

- 7.1. Any **authorised practitioner** on leave from their practice should advise the DOH in writing if they wish for alternative arrangements to be made. Information provided should include the time period on leave, the name of the locum consultant and, where they have not nominated a co-prescriber, whether a general medical practitioner, whose principal place of practice is in WA, may write an interim prescription.
- 7.2. A locum specialist practitioner should ensure they have an SPN and may continue to prescribe based on the *Notification of Treatment Using Stimulant Medication* or authorisation that the **authorised practitioner** has submitted. If they wish to prescribe outside the previously notified details, they will be required to submit a re-Notification.
- 7.3. If a locum authorised practitioner wishes to initiate treatment they will be required to complete a *Notification of Treatment Using Stimulant Medication* form. If they wish to prescribe outside the Stimulant Prescribing Code, they will be required to obtain an authorisation prior to initiating treatment.
- 7.4. Where an **authorised practitioner** has agreed to nominate a general medical practitioner, whose principal place of practice is in WA, to prescribe stimulant medicine in their absence, the general medical practitioner must obtain an interim authorisation from the CEO prior to writing a prescription. A copy of the authorisation will be sent to the authorised practitioner. An interim authorisation will be based on the treatment rationale previously notified by the authorised practitioner.
- 7.5. Where a *Notification of Treatment Using Stimulant Medication* form has not been received from, nor an authorisation issued to, an authorised practitioner, no interim authorisation will be issued to a general medical practitioner in their absence.

## 8. Public Sector Clinics

- 8.1. A public sector clinic located in WA may apply to be registered as a stimulant prescribing clinic by submitting the form 'Application to Register a Public Clinic' to the DOH.
- 8.2. An application must nominate an authorised practitioner practising at the clinic or another senior member of staff such as the manager of the clinic, to be responsible for corresponding with the DOH.
- 8.3. The manager of the clinic must notify the CEO of any authorised practitioners who commence or cease to practise at the clinic, and of any changes in the name or address of the clinic.

- 8.4. The CEO must be notified of any change in the manager of the clinic by the former manager, new manager or an authorised practitioner of the clinic within 14 days of the change.
- 8.5. An **authorised practitioner** who commences stimulant treatment of a patient at a registered public clinic can submit a *Notification of Treatment Using Stimulant Medication* form to the DOH, or apply for authorisation to prescribe, for a particular patient on behalf of the clinic.
- 8.6. If a patient is seen at the same clinic by a different authorised practitioner, a new *Notification of Treatment Using Stimulant Medication* form will not be required.
- 8.7. If the patient's treatment requires amendment, a re-Notification on behalf of the clinic must be submitted. The re-Notification may be submitted by any of the authorised practitioners of the clinic.