Australian Capital Territory

Medicines, Poisons and Therapeutic Goods (CHO decisions on applications) Guidelines 2014 (No 1)

Notifiable instrument NI2014–375

made under the

Medicines, Poisons and Therapeutic Goods Regulation, section 574 (Medicines Advisory Committee – guidelines for CHO decisions on applications)

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1 Name of instrument

This instrument is the *Medicines, Poisons and Therapeutic Goods (CHO decisions on applications) Guidelines 2014 (No 1).*

2 Commencement

This instrument commences on the day after notification.

3 Purpose

The guidelines as set out in Schedule 1 are issued for the Chief Health Officer in relation to decisions on applications under section 560 of the Medicines, Poisons and Therapeutic Goods Regulation 2008 for approval to prescribe a controlled medicine.

4 Approval

The guidelines as set out in Schedule 1 are approved.

Dr Rashmi Sharma
Chair, Medicines Advisory Committee

31 July 2014

ACT Government
Health

Schedule 1

Medicines Advisory Committee - Guidelines for the Chief Health Officer

These guidelines are issued by the Medicines Advisory Committee for the Chief Health Officer in relation to decisions on applications for approval to prescribe a controlled medicine under the Medicines, Poisons and Therapeutic Goods Regulation 2008.

1. Applications for Chief Health Officer approval to prescribe amphetamines for Attention Deficit Hyperactivity Disorder

The following criteria are issued to the Chief Health Officer for making a decision on an application for approval to prescribe amphetamines for ADHD.

1.1. Patients aged less than four years

Applications for approval to prescribe amphetamines for ADHD in patients aged less than four years should only be considered if:

- treatment is to be initiated by a paediatrician, appropriate psychiatrist or neurologist; and
- treatment is supported by a second such specialist opinion before being referred to the Medicines Advisory Committee for determination.

Subsequent applications for continuing treatment with amphetamines should be submitted to the Chief Health Officer by the initiating specialist.

1.2. Patients aged between 4 and 19 years

Applications for approval to prescribe amphetamines for ADHD in patients aged between 4 and 19 years should only be considered if:

- treatment is initiated by a paediatrician, appropriate psychiatrist or neurologist.

Subsequent applications for continuing treatment with amphetamines should be considered if:

- submitted by a paediatrician, appropriate psychiatrist or neurologist; or
- submitted by a general practitioner, and the efficacy of the prescribed treatment has been reviewed by a paediatrician, psychiatrist or neurologist within the previous two years.

1.3. Patients aged 19 years or older

Applications for approval to prescribe amphetamines for ADHD in patients aged 19 years or older should only be considered if:

- treatment is initiated by an appropriate psychiatrist or neurologist.

Subsequent applications for continuing treatment with amphetamines should be considered if:

- submitted by a appropriate psychiatrist or neurologist; or
- submitted by a general practitioner where:
  - the efficacy of the prescribed treatment has been reviewed by a psychiatrist or neurologist within the previous three years; and
  - there is no prescribed increase in dose.

Note: Any increase to a patient's dose should only be prescribed by an appropriate psychiatrist or neurologist.

2. ADHD Criteria for Diagnosis

The following criteria should be considered when diagnosing ADHD in conjunction with **DSM-IV** or **DSM-V** criteria:

(1) A childhood history characterised by clear-cut hyperactivity and/or attention problems with at least one of the following symptoms/signs:
- behaviour and/or attention problems at school;
- impulsivity;
- over excitability;
- temper outbursts.

(2) The continuing presence in adulthood of hyperactivity and/or inattentiveness together with at least two of the following six characteristics:
- affective lability;
- disorganisation and inability to complete tasks;
- hot temper;
- impulsivity;
- easily distracted;
- major problems with short-term memory

(3) Evidence that the condition is long standing and clinically severe in terms of dysfunction.

(4) Symptoms are continuous – not related to stress or crises.

Note: Whilst co-morbidity (e.g. depression, anxiety/panic, affective disorder) often exists, ADHD should be the most prominent disorder.