ACT Government
Health

Australian Capital Territory

Medicines, Poisons and Therapeutic Goods (Category Approval) Determination 2018 (No 1)

Notifiable instrument NI2018-77

made under the

Medicines, Poisons and Therapeutic Goods Regulation, section 575 (Category approval determination)

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1 Name of instrument

This instrument is the *Medicines, Poisons and Therapeutic Goods (Category Approval) Determination 2018 (No 1).*

2 Commencement

This instrument commences on the day after its notification day.

4 Revocation

This instrument revokes the *Medicines, Poisons and Therapeutic Goods (Category Approval) Determination 2017 (No 3*) - NI2017-559.

5 Approval

In accordance with section 575 of the Medicines, Poisons and Therapeutic Goods Regulation 2008 (Category approval determination), the Chief Health Officer may determine circumstances in which category approval to prescribe a controlled medicine may be given. The Controlled Medicines Prescribing Standard determination is set out in Schedule 1.

Dr Paul Kelly
Chief Health Officer

19 February 2018

ACT Government
Health

Schedule 1

Controlled Medicines Prescribing Standards

These Controlled Medicines Prescribing Standards (Prescribing Standards) are made under the Medicines, Poisons and Therapeutic Goods Regulation 2008 for the purposes of establishing the conditions and criteria under which a prescriber may prescribe a controlled medicine under a Chief Health Officer (CHO) category approval or drug approval.

These Prescribing Standards should be read in conjunction with the *Medicines, Poisons and Therapeutic Goods Act 2008* and the Medicines and Poisons and Therapeutic Goods Regulation 2008 (from www.legislation.act.gov.au) to ensure prescribers are fully aware of their obligations in prescribing a controlled medicine and applying for CHO controlled medicines approval.

For further information regarding these prescribing standards please contact the Health Protection Service on 6205 1700 or at HPS@act.gov.au.

A key regulatory control under the Medicines, Poisons and Therapeutic Goods Regulation 2008 (the Regulation) relates to CHO approvals. The Regulation requires prescribers to apply to the CHO for approval prior to prescribing a controlled medicine for a drug dependent person or for ongoing therapy of longer than two months.

A prescriber **does not** need to apply for Chief Health Officer (CHO) approval **if all** of the following criteria are met:

- the prescriber believes on reasonable grounds that the person is **not a drug dependent person**;
- the prescriber believes on reasonable grounds that the person has not been prescribed **any controlled medicines within the previous 2 months**; and
- the prescriber expects that the person will only need to use the prescribed controlled medicine for **less than 2 months**.

If any of the above criteria are **not met**, the prescriber **must apply** for CHO approval.

Prescribers have the ability to apply for either:

1. Controlled medicine approval by category

CATEGORY 1 (page 3)

- Controlled medicine to treat a person with chronic (non-cancer) pain.

CATEGORY 2 (page 5)

- Controlled medicine to treat a person with pain directly attributable to:
  - active malignancy or life limiting disease state or considered on a case by case basis; and
  - where the prognosis might reasonably be expected to be 12 months or less.

CATEGORY 3 (page 8)

- Controlled medicine to treat a person with drug-dependency.

CATEGORY 4 (page 11)

- Controlled medicine to treat a person with a licensed indication or severe insomnia.

CATEGORY 5 (page 12)

- Controlled medicine to treat a person with Attention Deficit Hyperactivity Disorder.

CATEGORY 6 (PAGE 15)

- Controlled medicine to treat a person with medicinal cannabis for listed indications.

2. Controlled medicine approval by drug

This is where the requested drug's dose, form and strength and the person's condition must be specified. For example, due to prescriber preference; or seeking to treat a person with a controlled medicine at a dosage or for a condition not covered under *controlled medicine approval by category*.

Controlled medicine approval by category

CATEGORY 1

Controlled medicine to treat a person with chronic (non-cancer) pain

Approval under this category allows a prescriber to prescribe a controlled medicine to a non drug dependent person with chronic (non-cancer) pain, for a maximum of 12 months if:

The person's total daily oral morphine equivalent dose (MEqD) [as measured in milligrams (mg)] of prescribed opioids is **equal to, or less than 100mg MEqD^**.

This category approval does not include injectable opioid controlled medicines, methadone or fast acting fentanyl oral dose formulations.

This category approval applies for controlled medicine treatment longer than two months.

Oral morphine equivalent dose (MEqD)			
Drug	**Formulations**	***Conversion ratio~***	***MEqD 100mg (daily)***
Morphine	oral (mg/day)	1 : **1**	100mg
Hydromorphone	oral (mg/day)	1 : **5**	20mg
Buprenorphine	transdermal (microg/hr)	1 : **2**	50mcg/hr
Fentanyl	transdermal (microg/hr)	1 : **3.6**	28mcg/hr
Oxycodone	oral (mg/day)	1 : **1.5**	66mg
Tapentadol	oral (mg/day)	1 : **0.4**	250mg

~ *Source: Australian Medicines Handbook 2016*

A MEqD calculator can be found on the ACT Health, Pharmaceutical Services website http://www.health.act.gov.au/public-information/businesses/pharmaceutical-services

Other Information

This category approval is inclusive of any controlled medicine approval given by category or drug for chronic (non-cancer) pain. That is, this category approval will not be approved in addition to a separate approval for *controlled medicine by drug approval* to treat a person with chronic (non-cancer) pain.

This category approval permits more than one opioid controlled medicine being prescribed at a time and allows for opioid rotation and titration of dose, provided that the person's total dosage is equal to, or less than 100mg MEqD^.

The CHO may ask for further information when considering this application, including but not limited to seeking evidence of appropriate specialist (that is, a pain or addiction specialist or addiction psychiatrist) support. The specialist review must have occurred within the previous 2 years.

When considering an application the CHO may choose to refuse, amend or place a condition on an application if the CHO believes that it is in the best interests of the patient or the public to do so.

^ 100mg MEqD has been selected based upon current best practice outlined in reference below:

- NPS. (2015). *Best Practice Opioid Analgesic Prescribing for Chronic Pain.* Retrieved from http://www.nps.org.au/conditions/nervous-system-problems/pain/for-individuals/pain-conditions/chronic-pain/for-health-professionals/opioid-medicines/best-practice-prescribing
- Royal Australian College of General Practitioners. (2015). *Prescribing drugs of dependence in general practice, Part A Clinical governance framework, D. 9 Practice Policy – Opioid dosing thresholds.* Retrieved from http://www.racgp.org.au/your-practice/guidelines/drugs-of-dependence-a/appendix-d-example-practice-policies/d9-practice-policy-%E2%80%93-opioid-dosing-thresholds/
- Faculty of Pain Medicine ANZCA. (2015). *Recommendations regarding the use of Opioid Analgesics in patients with chronic Non-Cancer Pain.* Retrieved from http://fpm.anzca.edu.au/documents/pm1-2010.pdf
- Currow, D.C., Phillips, J., Clark, K. (2016) Using opioids in general practice for chronic non-cancer pain: an overview of current evidence. *Medical Journal of Australia, 204* (8): 305-309.

In addition, this opioid threshold is reasonably comparable to the 90mg MEqD limit contained within the :

- Centre for Disease Control and Prevention. (2016). *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016.* Retrieved from http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

Recommendation:

When the person's total daily dose is between **40 – 50mg MEqD**, the prescriber should consider additional precautionary measures. For example, the prescriber could consider referring the person to an appropriate specialist (that is, a pain or addiction specialist or addiction psychiatrist) for consultation. Other precautionary measures could also include staged supply arrangements and/or a Voluntary Undertaking .

Note: 40 – 50 mg MEqD has been selected based upon current best practice outlined in the Faculty of Pain Medicines ANZCA Recommendations regarding the use of Opioid Analgesics in persons with chronic Non-Cancer Pain which suggests caution at total daily doses > 40mg MEqD and the CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016 which suggests a re-assessment of individual benefits and risks for total daily doses ≥ 50mg MEqD.

When to apply for *controlled medicine approval by drug*

Prescribers are advised that a **Category 1** approval is not available when:

1. a person's total daily dose is **above 100mg MEqD**;

Applications to prescribe opioids in doses greater than 100mg MEqD will not be approved unless made by, or include documented support from a pain or addiction specialist; geriatrician; or addiction psychiatrist.

The need for support from a specialist mentioned above does not apply for applications submitted for any of following patient groups:

a) In-patients of residential care facilities for all indications, for doses less than 300mg MEqD, where it is not practical for the prescriber to obtain a specialist review.

b) Patients who are experiencing acute on chronic exacerbation(s) of pain. Approvals may be issued for up to 8 weeks, following which specialist support would be required if dose reduction was unsuccessful.

c) Patients who have a comprehensive pain management plan in place and where the plan proposes to reduce the patient's use of opioids to below 100mg MEqD.

Approvals may be issued for up to three months, following which support from a specialist mentioned above will be required if the dose reduction is unsuccessful. Subsequent approvals may be granted (up to a maximum of 6 months from commencement of a reduction plan) if dose reduction is successful but not yet less than 100mg MEqD.

2. treating a **drug dependant** person with chronic (non-cancer) pain; treating a non-drug dependent person for chronic (non-cancer) pain with any methadone formulation;

Applications to prescribe opioids to a drug-dependent person will not be approved unless made by, or include documented support from a pain or addiction specialist; or addiction psychiatrist.

3. treating a non-drug dependent person for chronic (non-cancer) pain with fast acting fentanyl oral dose formulations;

Applications to prescribe a fast acting fentanyl oral dose formulation will not be approved unless made by, or include documented support from a pain or addiction specialist; or addiction psychiatrist.

4. treating a non-drug dependent person for chronic (non-cancer) pain with injectable opioid controlled medicines;

Applications to prescribe an injectable opioid controlled medicine will not be approved unless made by, or include documented support from a pain or addiction specialist; or addiction psychiatrist.

5. treating a person for intestinal conditions with codeine; or

Applications to prescribe codeine for intestinal conditions will not be approved unless made by, or include documented support from a pain or addiction specialist; or addiction psychiatrist.

6. treating an indication not listed on the Australian Register of Therapeutic Goods.

Applications to prescribe a controlled medicine for an indication not listed on the Australian Register of Therapeutic Goods will not be approved unless a signed patient consent form is attached to acknowledge the treatment is for a non-licensed condition

CATEGORY 2

Controlled medicine to treat a person with pain directly attributable to:

- **active malignancy or life limiting disease state; or**
- **considered on a case by case basis; and**
- **where the prognosis might reasonably be expected to be 12 months or less.**

This Category is for any prescriber (other than a pain, addiction or palliative care specialist, oncologist, credentialed general practitioner#, palliative care registrar, palliative care nurse practitioner or other specialist as considered appropriate)

Approval under **Category 2A** and **2B** a prescriber may prescribe a controlled medicine to a non drug dependent person, for a maximum of 12 months if:

Category 2A

The person's total daily oral morphine equivalent dose (MEqD) mg of prescribed opioids is **equal to, or less than 160mg MEqD** ◊ (including injectable controlled medicines and fast acting fentanyl oral dose formulations) and evidence of the patients' active malignancy or life limiting disease state is provided.

Category 2B

The person's total daily oral MEqD of prescribed opioids is **equal to, or less than 300mg MEqD** ◊ (including injectable controlled medicines and fast acting oral dose formulation fentanyl) with appropriate specialist support^^^ (that is, a pain, addiction or palliative care specialist, oncologist, advanced training palliative care registrar, credentialed general practitioner#, palliative care nurse practitioner or other specialist as considered appropriate) for the requested dosing regimen and evidence of the patients' active malignancy or life limiting disease state is provided.

Concurrent approvals for a prescriber and appropriate specialist are permitted to treat a person with pain directly attributable to active malignancy or life limiting disease states.

This category approval applies for controlled medicine treatment longer than two months.

Oral morphine equivalent dose (MED)				
Drug	**Formulations**	***Conversion ratio~***	***MED 160mg*** *(daily)*	***MED 300mg*** *(daily)*
Morphine	oral (mg/day)	1 : **1**	160mg	300mg
Hydromorphone	oral (mg/day)	1 : **5**	32mg	60mg
Buprenorphine	transdermal (microg/hr)	1 : **2**	80mcg/hr	150mcg/hr
Fentanyl	transdermal (microg/hr)	1 : **3.6**	45mg/hr	84mcg/hr
Oxycodone	oral (mg/day)	1 : **1.5**	107mg	200mg
Tapentadol	oral (mg/day)	1 : **0.4**	400mg	750mg

~Source: Australian Medicines Handbook 2016

A MEqD calculator can be found on the ACT Health, Pharmaceutical Services website http://www.health.act.gov.au/public-information/businesses/pharmaceutical-services

^^^ When seeking specialist support under 2B prescribers may choose to consult with an appropriate specialist via telephone or email should a face-to-face review of the patient not be practicable.

A Credentialed General Practitioner is a general practitioner whose palliative care experience and training is recognised via endorsement by ACT Health

◊Based on expert advice from palliative care specialists at Clare Holland House.

Other Information

The above categories are inclusive of any controlled medicine approval given by category or drug. That is, the above categories will not be approved on top of an existing *controlled medicine by drug approval* to treat a person with pain directly attributable to active malignancy or life limiting disease state.

The above categories permit more than one controlled medicine being prescribed at a time, provided that the person's total daily dosage does not exceed the relevant *controlled medicine by category* provisions.

The CHO may ask for further information when considering this application, including but not limited to seeking evidence of specialist support (or support from another specialist). Should a face-to-face review not be practicable, prescribers may choose to consult an appropriate specialist via telephone or email and document the conversation appropriately.

When considering an application the CHO may choose to refuse, amend or place a condition on an application if the CHO believes that it is in the best interests of the patient or the public to do so.

When to apply for *controlled medicine approval by drug*

Prescribers are advised that a **Category 2A or 2B** approval is not available when:

1. prescriber who is not included in the following list is treating a person with pain directly attributable to active malignancy or life limiting disease state **with any methadone formulation:**
    - pain specialist;
    - addiction specialist/psychiatrist;
    - palliative care specialist;
    - oncologist;
    - palliative care registrar;
    - other specialist as considered appropriate;
    - credentialed general practitioner#; or
    - palliative care nurse practitioner.

In this circumstance, prescribers must apply for *controlled medicine approval by drug*. This application must include support from an appropriate specialist (that is, a pain, addiction or palliative care specialist, oncologist, palliative care registrar, credentialed general practitioner#, palliative care nurse practitioner or other specialist as considered appropriate) that clearly supports the requested dosing regimen and evidence of the person's active malignancy or life limiting disease state. If a current review is not available support for the dose regime can be obtained from an appropriate specialist via telephone or email should a face-to-face review not be practicable. **The CHO can issue a controlled medicine approval by drug for up to 12 months.**

A credentialed general practitioner is a general practitioner whose palliative care experience and training is recognised via endorsement by ACT Health

CATEGORY 2

Controlled medicine to treat a person with pain directly attributable to:

- **active malignancy or life limiting disease state; or**
- **considered on a case by case basis; and**
- **where the prognosis might reasonably be expected to be 12 months or less.**

This Category is for all pain, addiction or palliative care specialist, oncologist, credentialed general practitioner#, advanced training palliative care registrar, palliative care nurse practitioner or other specialist as considered appropriate

Approval under this category allows that is, a pain, addiction or palliative care specialist, oncologist, advanced training palliative care registrar, credentialed general practitioner#, palliative care nurse practitioner or other specialist as considered appropriate to prescribe a controlled opioid medicine (including injectable controlled medicines, methadone and fast acting oral dose formulation fentanyl) to a non drug dependent person, for a maximum of 12 months if:

Category 2C

The prescriber has formed the reasonable belief that a controlled medicine is needed to treat a person with pain directly attributable to active malignancy or life limiting disease state. The prescriber will need to provide evidence (that is, written confirmation) of the person's active malignancy or life limiting disease state, including any relevant details e.g. nature of malignancy or disease state.

Category 2 approvals can be held concurrently by two practitioners (e.g. general practitioner and an appropriate specialist) to treat a person with pain due to active malignancy or life limiting disease state.

This category approval applies for controlled medicine treatment longer than two months.

Other Information

This category approval permits more than one opioid controlled medicine being prescribed at a time and does not specify a maximum dosage.

The CHO may ask for further information when considering this application, including but not limited to seeking evidence of specialist support (or support from another specialist).

When considering an application the CHO may choose to refuse, amend or place a condition on an application if the CHO believes that it is in the best interests of the patient or the public to do so.

A Credentialed General Practitioner is a general practitioner whose palliative care experience and training is recognised by the ACT Palliative Care Network.

CATEGORY 3

Controlled medicine to treat a person with drug-dependency

Approval under this category allows an endorsed prescriber[Δ] or a non-endorsed prescriber (continuing treatment for 5 patients or less) to prescribe methadone, buprenorphine or buprenorphine/naloxone to a drug dependent person for treatment of drug dependency, for a maximum of 12 months▫ if:

CATEGORY 3A

The total daily oral dosage of methadone is **equal to, or less than 120mg**.

Unsupervised (take-away) doses of methadone are permitted as outlined in the following table for persons that have been clinically assessed as stable in treatment*. Requests to prescribe additional take-away doses, or to commence dosing earlier then permitted in the following table may be considered via an application for Approval by Drug.

Length of time in treatment (months)	Methadone	Comments
0-3	0	Exceptional circumstances may allow one dose
3-5	2 per week	Not consecutively
5-7	2 per week	Maximum 2 consecutive
7-9	3 per week	Methadone – maximum 2 consecutive
>9	4 per week	

CATEGORY 3B

The total daily oral dosage of buprenorphine is **equal to, or less than 32mg**.

Unsupervised (take-away) doses of buprenorphine/naloxone are permitted as outlined in the following table for persons that have been clinically assessed as stable in treatment*. Requests to prescribe additional take-away doses, or to commence dosing earlier then permitted in the following table may be considered via an application for Approval by Drug.

Length of time in treatment (months)	Buprenorphine/ naloxone	Comments
0-3	0	Exceptional circumstances may allow one dose
3-5	2 per week	Not consecutively
5-7	4 per week	Maximum 2 consecutive
7-9	6 per week	
9-12	13 per fortnight	2 weeks unsupervised dosing
>12	27 per 28 days	4 weeks unsupervised dosing

Unsupervised (take-away) dosing – special cases

Additional unsupervised (take-away) doses are permitted under a Category 3A and 3B approval for Easter, Christmas, New Year or other public holidays when supervised dosing is not available at the person's usual dosing pharmacy.

Additional unsupervised (take-away) doses are also permitted in instances where the person is required to travel interstate urgently and is unable to return to their usual pharmacy for supervised dosing for reasons outside their control. Examples include where there is a death in the client's family.

Additional take-away doses should be limited by prescribers and are permitted up to one occasion per month. Additional unsupervised doses are only available to a person who already receives unsupervised doses unless in exceptional circumstances.

Other Information

Controlled medicine approval applications will be considered in accordance with the *National Guidelines for Medication-Assisted Treatment of Opioid Dependence (2014)* (National Guidelines).Prescribers must prescribe in accordance with the National Guidelines under their approval. Further advice regarding the treatment of a drug-dependent person can also be found in the *Opioid Maintenance Treatment in the ACT: Local Policies and Procedures* available at http://www.health.act.gov.au/our-services/alcohol-and-other-drugs/opioid-maintenance-treatment.

Under this Category approval the person must remain on a single controlled opioid medicine in which the total daily oral dosage above is not exceeded.

The CHO may ask for further information when considering this application, including but not limited to seeking evidence of specialist support (or support from another specialist).

When considering an application the CHO may choose to refuse, amend or place a condition on an application if the CHO believes that it is in the best interests of the patient or the public to do so.

To receive unsupervised (take-away) doses, a person needs to be assessed by their medical practitioner as meeting stability criteria. A Client Stability Assessment Form and information to guide the assessment of a person's stability is provided in the *Opioid Maintenance Treatment in the ACT: Local Policies and Procedures* document available at http://www.health.act.gov.au/our-services/alcohol-and-other-drugs/opioid-maintenance-treatment.

When to apply for *controlled medicine approval by drug*

Prescribers are advised that an application for **Category 3A or 3B** is not available when:

1. the person's total daily dose is **above 120mg for methadone or 32mg for buprenorphine**;

   For an endorsed prescriber this application must include documented support from a second endorsed prescriber that clearly supports the requested dosing regime.

   A non-endorsed prescriber must include documented support from an addiction specialist or addiction psychiatrist or endorsed prescriber with the application that clearly supports the requested dosing regime.

2. applying to prescribe outside the *National Guidelines for Medication-Assisted Treatment of Opioid Dependence (2014)*;
3. a person with drug-dependency requires treatment for an acute pain condition with another controlled medicine;

   A non-endorsed prescriber must include documented support from an addiction specialist or addiction psychiatrist or endorsed prescriber with the application that clearly supports the requested dosing regime.

4. a person with drug dependency requires **methadone tablets or additional supply of buprenorphine** due to the person being away from the ACT (e.g. interstate or overseas and where the patient cannot reasonably be dosed at an appropriate healthcare setting);
5. a person requires a greater number of unsupervised (take-away) doses than provided for in Category 3A or 3B or

   In this circumstance the prescriber must provide details of the person's stability assessment of the client being sufficiently stable using the Client Stability Assessment form available in Opioid Maintenance Treatment in the ACT: Local Policies and Procedures document available at http://www.health.act.gov.au/our-services/alcohol-and-other-drugs/opioid-maintenance-treatment.

6. a person requires buprenorphine for unsupervised (take-away) dosing; or
   In this circumstance the prescriber must provide details of the person's confirmed allergy to naloxone or the pregnancy.

7. treating an indication not listed on the Australian Register of Therapeutic Goods.
   In this circumstance patients must sign a consent form acknowledging treatment for a non-licensed condition.

In these circumstances the prescriber must apply for *controlled medicine approval by drug*. The CHO can issue a controlled medicine approval by drug for up to 12 months.

▫ Based on expert advice from alcohol and drug specialists at the ACT Alcohol and Drug Service

Δ An endorsed prescriber is a prescriber who has completed designated training as outlined in the Medicines, Poisons and Therapeutic Goods (Guidelines for treatment of opioid dependency) Approval 2017 (No 1) and been granted endorsement to treat-drug dependency by the Chief Health Officer under section 581 of the Medicines, Poisons and Therapeutic Goods Regulation 2008.

* These unsupervised (take-away) limits are based on long held principles determined in close consultation with local stakeholders within the alcohol, tobacco and other drug sector.

CATEGORY 4

Controlled medicine to treat a person with a licensed indication or severe insomnia

Under this category approval a specialist may prescribe a controlled medicine to a non drug dependent person, up to a maximum of 12 months if:

CATEGORY 4A

The specialist (that is, a psychiatrist) is treating a person with panic disorder or short term symptomatic treatment of anxiety (that is, a licensed ARTG indication) with **alprazolam** up to 10mg daily~.

CATEGORY 4B

The specialist (that is, a psychiatrist, neurologist or sleep medicine specialist) is treating a person with severe insomnia with **flunitrazepam** up to 2mg at night~.

This category approval applies for controlled medicine treatment longer than two months.

~ Source: Australian Medicines Handbook 2016

Other Information

It is recommended that a person has annual psychiatric reviews with an aim to discontinue alprazolam use.

The CHO may ask for further information when considering this application, including but not limited to seeking evidence of specialist support (or support from another specialist).

When considering an application the CHO may choose to refuse, amend or place a condition on an application if the CHO believes that it is in the best interests of the patient or the public to do so.

When to apply for *controlled medicine approval by drug*

Prescribers are advised that an application for **Category 4A or 4B** is not available:

1. for a prescriber (other than a psychiatrist) to prescribe alprazolam to treat a person for a licensed ARTG indication;

   This application must be accompanied by documented support from an appropriate specialist (that is, a psychiatrist) that clearly supports the requested dosing regimen and indication.

2. for a prescriber (other than a psychiatrist) to prescribe flunitrazepam for severe insomnia;

   This application must be accompanied by documented support from an appropriate specialist (that is, a psychiatrist, neurologist or sleep medicine specialist) that clearly supports the requested dosing regimen and condition.

3. for a specialist prescriber (psychiatrist, neurologist or sleep medicine specialist) to treat a person with alprazolam for a licensed ARTG indication with a daily dosage in excess of 10mg daily;

4. for a specialist prescriber (psychiatrist, neurologist or sleep medicine specialist) to treat a person with flunitrazepam for severe insomnia with a daily dosage in excess of 2mg at night; or

5. treating an indication not listed on the Australian Register of Therapeutic Goods.

   In this circumstance patients must sign a consent form acknowledging treatment for a non-licensed condition.

In these circumstances the prescriber must apply for *controlled medicine approval by drug*. The CHO can issue a controlled medicine approval by drug for up to 12 months

CATEGORY 5

Controlled medicine to treat a person with Attention Deficit Hyperactivity Disorder

For all prescribers other than a paediatrician, psychiatrist or neurologist

Under this category approval a prescriber may prescribe a controlled medicine to a non drug dependent person with Attention Deficit Hyperactivity Disorder (ADHD), up to a maximum of 2 years if:

CATEGORY 5A

Persons aged 4 to 18 years have been initiated or reviewed by a paediatrician, psychiatrist or neurologist within the previous two years.

This category approval is only inclusive of the total daily dosage as specified below:

- 40mg daily of dexamphetamine (dexamfetamine)
- 70mg daily of lisdexamphetamine
- 72mg daily of controlled release methylphenidate
- 60mg daily of conventional methylphenidate.

CATEGORY 5B

Persons aged 19 years or older have been initiated or reviewed by a psychiatrist or neurologist within the previous three years.

This category approval is only inclusive of the total daily dosage as specified below:

- 40mg daily of dexamphetamine (dexamfetamine)
- 70mg daily of lisdexamphetamine
- 72mg daily of controlled release methylphenidate
- 60mg daily of conventional methylphenidate.

Applications made by prescribers (other than a paediatrician, psychiatrist or neurologist) must be accompanied by documented support from an appropriate specialist (that is, a paediatrician, psychiatrist or neurologist) that clearly supports the requested dosing regimen and ADHD diagnosis.

This category approval applies for controlled medicine treatment longer than two months.

Other Information

The above categories permit a prescriber to prescribe **one long acting** and **one short acting** controlled medicine to treat a person with ADHD provided that the maximum daily dose does not exceed the above and that this dosing regimen is supported by an appropriate specialist.

The above categories do not permit a prescriber to initiate an increase in dose or change in stimulant controlled medicine without appropriate specialist support.

The above categories exclude persons aged less than four years.

The CHO may ask for further information when considering this application, including but not limited to seeking evidence of specialist support (or support from another specialist).

When considering an application the CHO may choose to refuse, amend or place a condition on an application if the CHO believes that it is in the best interests of the patient or the public to do so.

When to apply for *controlled medicine approval by drug*

Prescribers are advised that an application for **Category 5A or 5B** is not available:

1. for a prescriber (other than a paediatrician, psychiatrist or neurologist) to treat a person with ADHD at a dosage in excess of any of the total daily dosages listed above or for treatment of a condition other than ADHD;
2. patients under 4 years of age; or
3. for any prescriber applying to prescribe a controlled medicine to treat for a non-licensed indication through the Australian Register of Therapeutic Goods.
   In this circumstance patients must sign a consent form acknowledging treatment for a non-licensed condition.

In this circumstance the prescriber must apply for *controlled medicine approval by drug*. This application must be accompanied by documented support from an appropriate specialist (that is, a paediatrician, psychiatrist or neurologist) that clearly supports the requested dosing regimen and condition.

CATEGORY 5

Controlled medicine to treat a person with Attention Deficit Hyperactivity Disorder

For a paediatrician, psychiatrist or neurologist or any other specialist considered appropriate

Under this category approval a specialist [that is, a paediatrician (for persons aged between 4 and 19), psychiatrist or neurologist] may prescribe a controlled medicine to a non drug dependent person with ADHD, up to a maximum of 3 years for:

CATEGORY 5C

Persons aged 4 to 18 years

This category approval is only inclusive of the total daily dosage below:

- 40mg daily of dexamphetamine (dexamfetamine)
- 70mg daily of lisdexamphetamine
- 72mg daily of controlled release methylphenidate
- 60mg daily of conventional methylphenidate.

CATEGORY 5D

Persons aged 19 years or older

This category approval is only inclusive of the total daily dosage below:

- 40mg daily of dexamphetamine (dexamfetamine)
- 70mg daily of lisdexamphetamine
- 72mg daily of controlled release methylphenidate
- 60mg daily of conventional methylphenidate.

This category approval applies for controlled medicine treatment longer than two months.

Other Information

The above categories permit a prescriber to prescribe one long acting and one short acting controlled medicine to treat a person with ADHD provided that the maximum daily dose does not exceed the above.

The above categories exclude persons aged less than four years.

The CHO may ask for further information when considering this application, including but not limited to seeking evidence of specialist support (or support from another specialist).

When considering an application the CHO may choose to refuse, amend or place a condition on an application if the CHO believes that it is in the best interests of the patient or the public to do so.

Note: Diagnosis of ADHD should be considered in conjunction with any ADHD diagnostic criteria as set out in the *Diagnostic and Statistical Manual of Mental Disorders - 4th Edition* (DSM-IV), or *the Diagnostic and Statistical Manual of Mental Disorders - 5th Edition* (DSM-V) or the latest edition.

When to apply for *controlled medicine approval by drug*

Prescribers are advised that an application for **Category 5C or 5D** is not available:

1. for a specialist prescriber (paediatrician, psychiatrist or neurologist) to treat a person with ADHD at a dosage in excess of any of the total daily dosages listed above or for treatment of a condition other than ADHD;
2. for a specialist prescriber (paediatrician, psychiatrist or neurologist) to treat a person with ADHD aged less than 4 years; or

   This application must include documented support from the second specialist that is a (paediatrician, psychiatrist or neurologist). The CHO will refer this application to the Medicines Advisory Committee.

3. treating an indication not listed on the Australian Register of Therapeutic Goods.
   In this circumstance patients must sign a consent form acknowledging treatment for a non-licensed condition.

In these circumstances the prescriber must apply for *controlled medicine approval by drug*. The CHO can issue a controlled medicine approval by drug for up to 12 months

CATEGORY 6

Cannabis products for medicinal purposes (as controlled medicines – see next page) to treat a person with indications directly attributable to:

- **spasticity in multiple sclerosis;**
- **nausea and vomiting related to cancer chemotherapy;**
- **pain and/or anxiety in patients with active malignancy or a life limiting disease state where the prognosis might reasonably be expected to be 12 months or less; and/or**
- **Refractory paediatric epilepsy.**

Prescriber

Under this category approval, a prescriber may prescribe a cannabis product(s) to a non-drug dependent person, up to a maximum of 12 months for:

CATEGORY 6A

Indications directly attributed to spasticity in multiple sclerosis

A neurologist or *general practitioner with documented support of a neurologist may be approved under this category.

CATEGORY 6B

Indications directly attributed to nausea and vomiting related to cancer chemotherapy

An oncologist, palliative care specialist/registrar, #credentialed general practitioner, palliative care nurse practitioner or *general practitioner with documented support of an oncologist or palliative care specialist may be approved under this category.

CATEGORY 6C

Indications directly attributed to pain and/or anxiety in patients with a) active malignancy or b) a life limiting disease where (in either case) the prognosis might reasonably be expected to be 12 months or less

A palliative care specialist/registrar, pain specialist, addiction specialist, psychiatrist, palliative care nurse practitioner, oncologist or *general practitioner with documented support from a palliative care specialist, pain specialist, addiction specialist, psychiatrist, or oncologist may be approved under this category.

CATEGORY 6D

Indications directly attributed to refractory paediatric epilepsy

A paediatrician and/or neurologist may be approved under this category.

This category approval applies for controlled medicine treatment longer than two months.

*Where the prescriber is a general practitioner, evidence of support from an appropriate specialist in the condition to be treated must be provided with an application.

A Credentialed General Practitioner is a general practitioner whose palliative care experience and training is recognised via endorsement by ACT Health

Medicinal Cannabis as a Controlled Medicine

In order to be considered a schedule 8 controlled medicine, medicinal cannabis products must be:

a) cultivated or produced, or in products manufactured, in accordance with the *Narcotic Drugs Act 1967*; and/or

b) for use in products manufactured in accordance with the *Narcotic Drugs Act 1967*; and/or

c) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the *Therapeutic Goods Act 1989*; and/or

d) in therapeutic goods supplied in accordance with the *Therapeutic Goods Act 1989*,

except when:

i) it is a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the Therapeutic Goods Regulations 1990 applies; or

ii) separately specified in Schedule 4; or

iv) in hemp seed oil for purposes other than internal human therapeutic use containing 50 mg/kg or less of cannabinoids.

Reference: The Poisons Standard November 2016. https://www.legislation.gov.au/Details/F2016L01638

Application requirements

Prescribers are advised that an application for **Category 6A, 6B, 6C or 6D** must fulfil the following criteria:

1. The prescriber must be a medical practitioner with specialist knowledge (or in the case of a general practitioner, include documented support of an appropriate specialist) relating to the condition to be treated.
2. The prescriber must provide sufficient evidence and information regarding the form, composition, administration route, dosage and condition to be treated in order for delegates of the CHO to process the application.
3. The prescriber must hold, or have applied for, an authorisation by the Secretary of the Commonwealth Department of Health (or delegate) to access and/or supply that particular product in accordance with the Commonwealth:
   - Authorised Prescriber Scheme, or
   - Special Access Scheme Category A or Category B, or
   - Clinical Trial Scheme, or
   - Personal importation.
4. The prescriber must have obtained written patient consent.
5. The Application to Prescribe Medicinal Cannabis Form must be completed in full and include form, composition, administration route, dosage and relevant government authorisations.

Dosage

In the absence of registration by the Therapeutic Goods Administration, the recommendation with all medicinal cannabis products is to 'start low and go slow'.

Quantitative dosing must be proposed by the prescriber in their application. Dosing must be relevant to the presentation and strength of the specified product (e.g. certain volume of liquid, or number of tablets to be taken at a specified frequency).

Many uses for medicinal cannabis products may involve empirical dose finding for individual patients. However, prescribers must be able to justify the proposed dosing range with reference to appropriate literature, product or other information.

When to apply for *controlled medicine approval by drug*

Prescribers are advised that a Category 6A, 6B, 6C or 6D approval is not available when:

1. Prescribing a medicinal cannabis product for an indication not listed in Category 6A, 6B, 6C or 6D.

In the above instance, prescribers should submit an Application for Approval to Prescribe Medicinal Cannabis form. Applications to prescribe a medicinal cannabis product may not be approved unless submitted by, or include documented support from an appropriate specialist in the condition to be treated.

2. Prescribing nabiximols.

In the above instance, prescribers should submit an Application for Approval to Prescribe a Controlled Medicine form. Applications to prescribe nabiximols may not be approved unless submitted by a neurologist or rehabilitation specialist.

Other Information

Other Approval and Permit Requirements

Therapeutic Goods Administration Approval to Prescribe

If a medicinal cannabis product is in schedule 8 of the SUSMP but is not included on the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Good Administration (TGA) (i.e. it is an unregistered medical product), then an exemption to prescribe an unregistered medicine is required from the TGA.

The ACT Government cannot issue a TGA exemption to prescribe an unregistered medicine.

For information on obtaining approval to prescribe unregistered medicines see the TGA website at www.tga.gov.au.

The TGA may request information from the ACT Government to assist with its decision whether to issue an authority to prescribe an unregistered medicine. The ACT Government will provide this information only if an applicant has indicated their consent to share information on an Application to Prescribe Medicinal Cannabis Form.

Prescribers may apply to the TGA and ACT Health concurrently, however ACT Health will not approve an application to prescribe medicinal cannabis until TGA approval is obtained.

Import permits

In order to prescribe a medicinal cannabis product that is manufactured overseas, a permit to import the product will be required from the Commonwealth Department of Health.

The ACT Government cannot issue a permit to import medicinal cannabis into Australia.

Information about applying for import permits for medicinal cannabis products can be obtained from the Office of Drug Control website at www.odc.gov.au.

For further information regarding these prescribing standards please contact the Health Protection Service on 6205 1700 or at HPS@act.gov.au