## Appendix 1. Prescribing medicinal cannabis products checklist

**Patient name:**

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**Patient address:**

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**Patient date of birth:**

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As most medical cannabis products are not registered for use in Australia, special federal (ie Therapeutic Goods Administration [TGA]) and state/territory governments approval are needed to prescribe. This checklist aims to assist general practitioners (GPs) in that approval process.

## Part A. Before prescribing medicinal cannabis products

When considering whether medicinal cannabis products should be prescribed, it is important to have a detailed discussion of the potential benefits and harms of the treatment with the patient. All identified risk factors should be appropriately discussed, and ensure proper and accurate documentation. The following information should be documented in the patient's clinical notes, and points should be considered and discussed with the patient before prescribing medicinal cannabis products:

- Family history
  - History of mental illness, especially schizophrenia
- Past medical history
  - History of mental illness, especially schizophrenia
  - History of dependence of drugs of dependence
  - History of hypersensitivity to cannabinoid or products
- Current medical history
  - Cardiovascular, liver and renal diseases
  - Pregnancy and/or breastfeeding
- Physical examination
- Medication review
  - Potential side effects of medicinal cannabis products
  - Potential drug–drug interaction with concurrent medication
- Social support
  - Unable to drive while using medicinal cannabis products
  - Employment, especially in employment with machinery (eg forklifts, buggies) or high-risk occupations (eg at heights)
  - Risk of falls
  - Family responsibilities and support
- Clinical justification for the use of the medicinal cannabis products
  - Seriousness of condition and symptoms
  - All conventional, evidence-based treatment options that have failed
  - Length of time that the failed treatment options were trialled
  - Reasons for ceasing the treatment options that have failed
  - Safety and efficacy data to support the proposed use of the medicinal cannabis products (eg clinical trials, peer-reviewed articles)

## Part B. Treatment plan for medicinal cannabis products

TGA rules require a treatment plan to include a trial period (eg four weeks) to determine the effectiveness and efficacy of medicinal cannabis products for the patient, especially for symptom control. There is no precise dosing when a doctor chooses to prescribe medicinal cannabis products, as it is dependent on the patient's characteristics.

The following information should be documented in the patient's clinical notes, and points should be considered and discussed with the patient in the creation of a treatment plan for patients commencing medicinal cannabis products:

- Treatment goals
  - Ideally be measurable at proposed intervals (eg reduction in vomiting in patients with cancer who are undergoing chemotherapy)
- Documentation of support from the patient's other specialist(s) who is/are involved in their care (as required by jurisdictional legislation)
- Dispensing
  - Note: It is important to obtain the cooperation of the community pharmacist before you consider prescribing medicinal cannabis products. When applying for approval, you are required to nominate an eligible pharmacist to dispense the medicinal cannabis products. Only medicinal cannabis products for a specific patient is able to be held in an approved community pharmacy.
  - Frequency of dispensing
  - Location of dispensing
- Monitoring and review
  - Review of the treatment plan at proposed intervals
  - Additional investigations
- Ceasing treatment
  - Adverse effects are not tolerated
  - Medicinal cannabis products are not helping
  - Treatment goals are not reached
- Informed consent
  - Refer to Parts C–F

## Part C. Use of medicinal cannabis products

1. What are the clinical reasons for consideration for the use of medicinal cannabis products in this patient, include seriousness of condition and symptoms, and specialist recommendation:

2. What are the treatment goals for the use of medicinal cannabis products, include trial period for review (Stop Rule):

3. Past therapies that have been trialled and failed, include reason(s) and length of time:

4. Outcomes and alternatives if medicinal cannabis products fails to achieve therapeutic goals and/or is ceased:

5. Medicinal cannabis type, dose, frequency and route of administration, and location of dispensing:

## Part D. Risks and side effects

### Unknown risks and late side effects

Medicinal cannabis products are still in an experimental phase of testing. There may be side effects and risks that are currently unknown. In the event that the use of medicinal cannabis products is ongoing, you will need to inform the patient/guardian of these risks and keep updated with any significant information regarding previously unknown risks. Possible side effects may include:

- Asthenia (abnormal physical weakness or lack of energy)
- Confusion, disorientation, dizziness, drowsiness, vertigo, sleepiness
- Balance problems, coordination
- Memory problems
- Diarrhoea
- Dry mouth
- Fatigue
- Hallucinations
- Vomiting or nausea

## Contraindications

Medicinal cannabis products are generally not appropriate for the following patients:

- Patients who have a history of hypersensitivity to any cannabis products
- Patients who have severe and unstable cardiopulmonary disease
- Patients who have risk factors for cardiovascular disease
- Patients who have a previous or current mental health condition
- Patients who are pregnant or breastfeeding

## Relative contraindications

Medicinal cannabis products should be carefully considered for the following patient:

- Patients who are aged 25 years or younger
- Severe liver disease
- Severe renal disease
- Misuse of drugs of dependence
- Interaction with other medications
- Paediatric and frail elderly patients with risk of falls

1. Potential risks associated with this specific patient, include family, and past and current medical histories:

2. Potential interaction(s) with this specific patient, include social and medication reviews:

3. Discussions, and questions and queries from the patient regarding medicinal cannabis products:

## Part E. Patient declaration and consent

I understand that by taking medicinal cannabis products, I must:

- ☐ Attend regular reviews with my doctor and others healthcare providers (eg allied health professionals, other specialists) as advised by my doctor
- ☐ Undertake regular blood tests
- ☐ Follow my doctor's advice on dosage and frequency
- ☐ Report any adverse effects to my doctor
- ☐ Avoid the use of illicit and unprescribed drugs
- ☐ Avoid the use of alcohol
- ☐ Avoid driving or use of machinery
- ☐ Report the effects of the medicinal cannabis products to my doctor

I confirm that my doctor discussed with me information on the:

- ☐ Reasons why medicinal cannabis products may be used
- ☐ Treatment goals for the use of medicinal cannabis products
- ☐ Previous treatments that have been trialled and failed
- ☐ Outcomes and alternatives if medicinal cannabis products fail to have the desired effects and/or are ceased
- ☐ Type, dose, frequency and route of administration, and location of dispensing of the medicinal cannabis
- ☐ Risks associated with the use of medicinal cannabis products
- ☐ Potential interaction with the use of medicinal cannabis products
- ☐ Questions and queries I have about the use of medicinal cannabis products

I acknowledge that:

- ☐ There can be no guarantee that medicinal cannabis products will improve my/my child's condition
- ☐ Medicinal cannabis products are not registered for use in Australia, but an application will be made for access approval under the provisions of the relevant legal and medical frameworks in my state/territory
- ☐ I agree that I can withdraw my consent and ask that medicinal cannabis products be withdrawn at any stage with the assistance of my doctor

**Patient/parent/guardian (print):**

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**Patient/parent/guardian (signature):**

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**Date:**

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## Part F. Doctor declaration

I declare I have personally discussed this form with the patient, including but not limited to, everything in parts A and B. I confirm that I gave the patient the opportunity to ask questions, which I have answered as fully as possible.

**Prescribing doctor (print):**

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**Prescribing doctor (signature):**

**Prescriber number:**

**Date:**