Medicines and Poisons Act 2019

Factsheet – current as at October 2024

Prescribing and dispensing unapproved medicinal cannabis

Background

Most medicinal cannabis products are 'unapproved' medicines as they have not been assessed for safety, quality and efficacy by the Therapeutic Goods Administration (**TGA**) and are not registered on the Australian Register of Therapeutic Goods (**ARTG**)[1;2].

As with all unapproved medicines, prescribers seeking to prescribe an unapproved medicinal cannabis product must obtain approval from the TGA either through the Special Access Scheme (**SAS**) or Authorised Prescriber (**AP**) Scheme. Queensland Health considers that the definition of 'supply[3]' in the *Therapeutic Goods Act 1989* (Cth) (**TG Act**)[4] can be extrapolated to encompass the activity of 'prescribing'. Further, that SAS and AP authorities operate to permit such 'prescribing' for the purposes of the TG Act. The TGA does not otherwise regulate prescribing of unapproved medicines. Prescribing of unapproved medicines within the bounds of the relevant TGA approval is subject to state and territory requirements.

TGA categories

Prescribers can make an application to access unapproved medicinal cannabis products via the SAS or AP pathway by active ingredient, rather than by trade name[5]. The TGA products are categorised by cannabinoid content as follows (**TGA category**)[6]:

- Category 1 CBD medicinal cannabis product (CBD ≥98%) – Schedule 4;
- Category 2 CBD dominant medicinal cannabis product (CBD ≥60% and <98%) – Schedule 8;
- Category 3 Balanced medicinal cannabis product (CBD <60% and ≥40%) – Schedule 8;
- Category 4 THC dominant medicinal cannabis product (THC 60–98%) – Schedule 8;
- Category 5 THC medicinal cannabis product (THC >98%) – Schedule 8.

[1] See: Australian Register of Therapeutic Goods (ARTG) | Therapeutic Goods Administration (TGA)

[2] Medicines which are registered on the ARTG are referred to as 'registered medicines' in the MPMR.

[3] The definition of 'supply' in the TG Act includes 'supply by way of administration to, or application in the treatment of, a person'.

[4] Federal Register of Legislation - Australian Government

[5] See: New streamlined process for medicinal cannabis applications | Therapeutic Goods Administration (TGA)

[6] See Medicinal cannabis products by active ingredients | Therapeutic Goods Administration (TGA)

While SAS and AP approvals are granted for medicinal cannabis categories, this does not change the requirements for a prescriber to write a lawful prescription in Queensland, as set out in sections 86 to 88 of the Medicines and Poisons (Medicines) Regulation 2021 (**MPMR**).

The Writing lawful prescriptions factsheet contains further guidance on these requirements.

Prescribing and dispensing unapproved medicinal cannabis products

Prescribers in Queensland

Under section 50 of the *Medicines and Poisons Act 2019* (**MPA**), medical practitioners and nurse practitioners that hold an SAS or AP approval[7] from the TGA to prescribe an unapproved medicinal cannabis product may do so in accordance with their TGA approval. No further Queensland approval is required.

However, prior to prescribing an unapproved schedule 8 (S8) medicinal cannabis product, all relevant practitioners must comply with section 41 of the MPA and they **must check QScript** (the monitored medicines database), which is the same requirement for all S8 medicines. The only exemptions to looking up QScript are under section 41(3) of the MPA, which includes when an exemption under Schedule 18, Part 1A of the MPMR applies.

Additionally, all prescribers of S8 medicinal cannabis products **must comply with the Monitored Medicines Standard.**

These requirements still apply even when an SAS or AP approval has been obtained through the TGA.

Interstate prescribers

Interstate medical practitioners and nurse practitioners seeking to prescribe unapproved medicinal cannabis for dispensing in Queensland must:

- be authorised to do so in the jurisdiction in which they are prescribing;
- have obtained an SAS or AP approval from the TGA;
- have obtained any required home state or territory approvals; and
- ensure the prescription contains the information detailed in sections 86-88 of the MPMR, to the extent the information is required under the sections for the medicine.

The Interstate prescriptions for dispensing in Queensland and Writing lawful prescriptions factsheets contain further guidance.

[7] NB: currently only medical practitioners can apply to the TGA to be an AP.

Content of a written prescription for unapproved medicinal cannabis

The name, form and strength of a medicine must be stated on the prescription under section 86(1)(h)–(i) of the MPMR.

Writing a **TGA category** on a prescription or a **strength range** of the medicine (e.g. THC 19–24%) does **not** meet the legislative requirement of section 86 of the MPMR.

Accordingly, a prescription with only a TGA category or a strength range stipulated cannot be lawfully dispensed by a dispenser in Queensland.

The prescription must also include how much of the medicine may be dispensed or given, including the number of repeats for the medicine, if any. A prescription that does not include a quantity is not compliant with section 86(1)(j) of the MPMR.

Prescribers should think carefully about the quantity to be dispensed and number of repeats when writing prescriptions, given the cost of the medicine and that some patients may not be able to pay for multiple units in one dispensing. If a prescriber writes a prescription for '30 grams and 3 repeats', a dispenser is not authorised to change this to '10 grams and 11 repeats' without agreement (and potentially a new prescription) from the prescriber.

Further, section 87(2)(b) of the MPMR stipulates that the interval between dispensing events for an S8 medicine must be at least one (1) day. Although the minimum dispensing interval is one (1) day, prescribers have a professional responsibility to ensure that the dispensing interval considers the patient's therapeutic needs. For example, prescribers should not select a dispensing interval that would supply a quantity of medicine that would last several weeks or months within the space of a few days, unless this is required for the patient's therapeutic needs.

Monthly totals

A monthly total amount is **not a legal requirement** on a prescription under the MPMR. However, Queensland Health understands that maximum monthly amounts are frequently written by prescribers on medicinal cannabis prescriptions. This amount generally reflects the monthly limit applied to the prescriber by their TGA approval under the AP scheme. Prescribers often write that the monthly limit is to apply across all medicinal cannabis products that they have prescribed for a particular patient, however if this detail is written on one prescription it cannot be applied across multiple different prescriptions for the same patient under Queensland legislation.

In addition to not being specifically provided for under Queensland legislation, the inclusion of monthly limits on medicinal cannabis prescriptions is challenging and burdensome for dispensers who do not have this same legal obligation which is placed on prescribers under a TGA approval.

For example, the term 'month' may be open to interpretation (e.g. within one 'calendar' month, or across multiple calendar months) unless the meaning is made clear by the prescriber. This may result in the patient taking their prescription to multiple differing dispensers, if one dispenser determines that the limit has been exceeded, but another does not. It is also problematic for dispensers as they have no reliable way of knowing exactly how much

medicinal cannabis has been dispensed for that patient in the month (however this is interpreted), because, firstly, patients may use multiple pharmacies, including interstate pharmacies, and this other dispensing information will not be available to the dispenser, and secondly, there is lack of consistent product coding for medicinal cannabis products, which may cause inaccuracies in how the dispensed medicinal cannabis product is recorded in QScript.

It is the **responsibility of the prescriber** to comply with any conditions or limitations imposed by the TGA approval granted to them, including monthly limitations on how much medicinal cannabis is authorised to be prescribed under the AP approval. These obligations are not imposed on the dispenser of the medicinal cannabis products.

If a dispenser is presented with a medicinal cannabis prescription with a monthly limit, the dispenser does not have a legal obligation to ensure that the prescriber is not prescribing a quantity over multiple prescriptions that exceeds this limit. However, the dispenser does have professional practice obligations to ensure that the supply of the medicine is safe and clinically appropriate.

Brand substitution

Under section 87(6) of the MPMR, a prescriber may state different forms of a particular type of S8 medicine but must not state more than one type of S8 medicine on a prescription. However, it is unclear what is considered the same 'type' of medicinal cannabis. Therefore, only one medicinal cannabis medicine can be written per prescription.

Medicinal cannabis medicines do not meet the requirements for 'generic medicines' under section 128 of the MPMR. A prescription for a medicinal cannabis medicine therefore cannot be substituted to an alternative brand by a dispenser. Similarly, a dispenser is not permitted to substitute a prescription for a medicinal cannabis medicine to an alternative medicine within the same TGA category. Where possible, it is recommended that the prescriber contacts the dispenser prior to prescribing to ensure the stock is available.

Medicinal cannabis prescriptions with potential substitutes are non-compliant. If the named product is unavailable and an alternative brand is required, a new prescription must be written, and the initial prescription should be cancelled.

If the named product is not available and an alternative medicinal cannabis medicine is required, the dispenser should contact the prescriber to request a new prescription. Dispensers cannot supply a medicine from a non-compliant prescription or if the instructions are unclear.

An electronic prescription can only have one medicine per prescription. A medicinal cannabis substitute written into the 'notes' or 'annotations' section of an electronic prescription does

not comply with the MPMR and is not deemed to be a separate prescribed item. Prescribers may utilise the 'annotation' function of the electronic prescription to flag to dispensers that, if the prescribed medicine is unavailable, they can contact the prescriber to request a new electronic prescription for the alternative medicine. For electronic prescriptions, if a substitute medicine is required to be dispensed, the prescriber must cancel and remake the prescription as per section 90(4) of the MPMR.

Amending medicinal cannabis prescriptions

There are situations where a dispenser may need to contact the prescriber to either make an amendment to a medicinal cannabis prescription, or to request a new prescription from the prescriber.

Under section 90 of the MPMR, a prescriber may amend an original written prescription for supply in one of the following ways:

- For a **handwritten** prescription, the prescriber must sign and date the amendment in a way that does not obscure the content of the original prescription.
- For a **computer-generated** prescription, the prescription must be amended on the computer and printed again.
- For an **electronic prescription** made in an electronic prescription management system, the prescription must be cancelled and remade.

A prescriber cannot amend an electronic prescription.
Section 90(4) of the MPMR specifically states that if a prescriber wishes to make a change to an electronic prescription, the prescription must be cancelled and remade in the prescribing system.

A dispenser is authorised to amend a written prescription (including an electronic prescription) under section 117 of the MPMR. The dispenser may amend the prescription before dispensing the medicine by **adding additional information** to the prescription **to clarify the prescriber's direction.**

The dispenser must:

- obtain consent to the amendment from the patient or person obtaining the medicine on their behalf; and
- have agreement to the amendment from the initial prescriber; and
- make the amendment in the way agreed by the prescriber and in a way that does not obscure any information on the prescription; and
- sign and date the amendment.

Dispensers must determine if the change they intend to make to the prescription meets the requirements of section 117 of the MPMR, or if a new prescription is required. This is dependent on the scenario and the dispenser must use their professional judgement.

Dispensers are not permitted to alter details to an electronic prescription during dispensing that could create errors when further repeats are processed. Examples include amending the

quantity, repeats, or medicine. Only the prescriber has the authority to make such changes to maintain consistency and prevent system errors.

Informed consent and Prescribing

When prescribing medicinal cannabis to a patient, prescribers must comply with any conditions imposed on a TGA approval relating to the medicinal cannabis product(s) being used, including obtaining informed consent in writing from the patient (or the person with the legal authority to consent to the treatment on behalf of the patient) in relation to the proposed use of the specified medicine. Informed consent should be freely given and obtained in line with good medical practice, and it should be in writing unless there are good reasons to the contrary.

It is important to ensure patients are aware of potential impacts that may result from their use of medicinal cannabis, including risks associated with the use of the medicinal cannabis products, drug interactions, reporting adverse events and restrictions on driving or the use of machinery.

Monitored medicines

Schedule 8 medicinal cannabis products are monitored medicines, and prescribers and dispensers must also comply with the relevant provisions of the MPA and MPMR related to prescribing, dispensing or giving a treatment dose of a monitored medicine.
See: https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/medicines/monitored-medicines/prescribing and Checking QScript (health.qld.gov.au)

Reporting requirements

Chapter 8, Part 5 of the MPMR requires people dealing with medicines to report particular matters to the chief executive in a range of circumstances (e.g., when the loss or theft of an S8 medicine is suspected, or when prescriptions or purchase orders are suspected to be unlawful e.g., false or fraudulent).

Information about these reporting requirements is available here - Reporting medicines matters to the chief executive | Queensland Health

If the circumstances you wish to report do not fit under any of the above requirements, e.g. non-compliant prescriptions, please complete the General report (Medicines) form, noting that the circumstances must relate to the MPA and/or MPMR.

Further, if you have particular concerns about the professional practice of another health practitioner, it is recommended that you consider whether you should make a notification to the Office of the Health Ombudsman (OHO) – further information regarding OHO notifications can be found here: https://www.oho.qld.gov.au/for-providers/make-a-notification.

For further information

Contact the Medicines Approvals and Regulation Unit (MARU)

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