Government of Western Australia
Department of Health

Guide for pharmacists dispensing medicinal cannabis

Background

Medicinal cannabis products are either Schedule 4 (S4) or Schedule 8 (S8) medicines. Medicinal cannabis products where cannabidiol (CBD) comprises <98% of the total cannabinoid content (including tetrahydrocannabinol (THC) or other cannabinoids naturally found in cannabis), and all formulations of cannabis, dronabinol, nabilone and nabiximols are S8 medicines.

Pharmacists must handle S8 cannabis-based products in the same manner as other S8 medicines.

At present, most medicinal cannabis products are not on the Australian Register of Therapeutic Goods (ARTG) and are therefore subject to alternative supply pathways, such as the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS) and Authorised Prescriber Scheme (AP).

As for all monitored medicines (S8 and S4 Monitored Medicines), prescribers must comply with the Monitored Medicines Prescribing Code when prescribing Schedule 8 medicinal cannabis products.

All prescriptions that are prescribed and/or dispensed in Western Australia (WA) must meet the requirements of the *Medicines and Poisons Act 2014*, the subsidiary Medicines and Poisons Regulations 2016 and the Monitored Medicines Prescribing Code (the Code).

Veterinarians cannot prescribe medicinal cannabis in S8 as the Poisons Standard schedule entry for medicinal cannabis products in S8 is limited to human therapeutic use.

Detailed information about medicinal cannabis for health professionals is available on the Department's website. Patients can find information about medicinal cannabis on the Healthy WA website.

Dispensing medicinal cannabis

- In Western Australia, all Australian Health Practitioner Regulation Agency (AHPRA) registered medical, and nurse, practitioners are eligible to prescribe medicinal cannabis products provided their professional registration does not have conditions or undertakings relevant to the prescribing of S8 or cannabis based medicines.
- Once a prescriber has received the required approvals from the TGA (and WA Health if this is needed as per the Code), they may write a prescription for medicinal cannabis for their patient.
- A patient can present their prescription to any pharmacy in Western Australia (WA) for dispensing.
- As with all S8 prescriptions, the pharmacist must confirm the authenticity of the prescription, the identity of the person presenting the prescription and the bona fides of the prescriber.
- All prescriptions must contain the essential elements of a prescription as required by Regulations 10 and 11 of the Medicines and Poisons Regulations 2016. The prescriber must clearly specify the exact product intended for supply. This includes the brand name, formulation, and the strength of each cannabinoid component (such as THC and CBD). The prescription must also include precise directions for use, detailing the dosage, frequency, and the maximum daily dose for each product. If multiple products are prescribed, the total maximum daily dose across all products must also be stated. Brand substitution is not permitted for medicinal cannabis products. See below *Substituting medicinal cannabis products.*
- All directions specified by the prescriber on the prescription must be included on the dispensing record and label, such as maximum daily doses and access limits particularly where multiple products are prescribed.

Reviewing ScriptCheckWA

- Pharmacists should review the patient's prescribing and dispensing history on ScriptCheckWA, as part of safe dispensing practice for monitored medicines, such as S8 medicinal cannabis products.
- Pharmacists are not required to actively check whether the prescriber has an authorisation from the WA Department of Health to prescribe S8 medicines, including S8 medicinal cannabis.
- Information about authorisations issued to prescribers are visible to pharmacists on ScriptCheckWA and may be helpful when making a professional decision about whether to contact the prescriber and/or dispense the prescription.
- If ScriptCheckWA shows an extreme risk patient alert, do not dispense the prescription and contact the Medicines and Poisons Regulation Branch on 9222 6883.
- If ScriptCheckWA indicates that the patient is participating in Community Program for Opioid Pharmacotherapy (CPOP), it is strongly recommended that the pharmacist consult with both the medicinal cannabis prescriber and the CPOP prescriber before dispensing the medicinal cannabis prescription.

- If a patient has been prescribed multiple medicinal cannabis products, pharmacists should consider the clinical appropriateness of the regime and discuss with the prescriber. Pharmacists should consider if the prescriptions are from the same, or multiple prescribers, and the clinical appropriateness of the overall regime to mitigate the risk of oversupply or inappropriate access.
- Pharmacists should check repeat intervals and access limits to ensure compliance, and review ScriptCheckWA, particularly for any dispensing activity outside their pharmacy.
- Pharmacists are required to practise safely and effectively in accordance with the AHPRA Code of Conduct. This includes applying clinical judgement to ensure the safe and appropriate supply of medicines, particularly where high THC dosing is concerned. Pharmacists can calculate the total THC dose using the guide available on the WA Health website, under the section titled "Calculating the total THC dose" on the Medicinal cannabis products (S4 and S8) page.
- The professional authority to dispense and supply medicines under the Medicines and Poisons Regulations 2016 is linked directly to registration as a pharmacist, and by reference, compliance with the AHPRA Code of Conduct.
- If there are concerns about the safety or appropriateness of supply, pharmacists are encouraged to contact the prescriber. It may be appropriate to request a management plan or discuss options to limit the patient's supply such as staged supply or revised repeat intervals. Any changes to repeat intervals must either be annotated directly on the prescription by the prescriber or issued as a new prescription reflecting the changes.

Substituting medicinal cannabis products

- Due to the broad range of medicinal cannabis products available, prescriptions for medicinal cannabis products must specify a particular product or brand.
- As medicinal cannabis products are not TGA approved, it is highly unlikely bioequivalence, meeting Australian regulatory standards, has been established between products and therefore unlikely that a dispensing pharmacist could substitute between products.
- If dispensing a product that is not bioequivalent to what is described in the original prescription, then a new prescription is required.
- If the prescriber instructs the pharmacist to supply an alternative product, the pharmacist can do so based on this direction. A new prescription is required for that supply.
- If the prescriber authorises a change, then they have an obligation to send a new prescription to the pharmacy.
- If a prescriber instructs a pharmacist to supply a S4 or S8 medicine via telephone or electronic communication, a covering prescription must be provided within 24 hours. For S8 medicines, if the covering prescription is not received within five working days, the pharmacist must notify the Department. No further repeats may be dispensed based on the original instruction until the prescription is received.

Compounding medicinal cannabis products

- Compounding of any product should be limited to situations where a suitable commercial product is not available. Given the broad range of cannabis-based products available through the TGA alternative supply pathways, compounding may not be appropriate for cannabis-based products.
- The TGA requires that pharmacists ensure each medicinal cannabis product compounded and dispensed complies with all requirements of TGO 93 and pharmacists must maintain records demonstrating this compliance. For further information: Complying with the quality requirements for medicinal cannabis (TGA) or contact the TGA.
- If compounding of a medicinal cannabis product is required, pharmacies do not require any additional licence or permit under the *Medicines and Poisons Act 2014*, to dispense prescriptions for medicinal cannabis that require compounding.
- Prescriptions for compounded medicinal cannabis must still contain the essential elements as required by Regulation 10 and 11 of the Medicines and Poisons Regulations 2016.
- Any starting materials used by the pharmacist to compound medicinal cannabis prescriptions must meet the criteria for cannabis in S8 or cannabidiol in S4 of The Poisons Standard (SUSMP).
- If the pharmacy uses separate software for compounding, pharmacists must ensure the dispensing transaction for each compounded preparation in S8 is via dispensing software that transmits dispensing data to the National Data Exchange (NDE). This is required to fulfil the Schedule 8 reporting requirements (in accordance with Regulation 143) and means the S8 dispensing transaction will be visible on ScriptCheckWA.
- Pharmacists should adhere to the Pharmacy Board of Australia's guidelines on compounding of medicines.
- The TGA's Special Access Scheme and Authorised Prescriber requirements are applicable to the prescribing of compounded medicinal cannabis preparations. Further information is available at: Medicinal cannabis reforms: Frequently asked questions | Therapeutic Goods Administration (TGA)

Interstate prescriptions

- Valid medicinal cannabis prescriptions issued by interstate prescribers may be dispensed in WA.
- For an interstate prescription to be valid in WA, prescriptions must include all the information normally required by the WA Medicines and Poisons legislation. For S8 prescriptions, this includes the patient's date of birth, exact repeat intervals and precise directions for use. For further information: Requirements for prescriptions in Western Australia.
- When dispensing interstate prescriptions for S8 medicines, pharmacists in WA must still take reasonable steps to confirm the authenticity of prescriptions, even if the patient presents a repeat prescription.

- Any remaining repeats for paper-based interstate S8 prescriptions must be retained at the dispensing WA pharmacy. If needed, these repeats can be transferred to a pharmacy in another state. Approval is not required to make this transfer. Repeats cannot be returned to the patient**.** For more information about the transfer of S8 prescription repeats, refer to: Transfer of Schedule 8 prescription repeats.

Ordering medicinal cannabis products

- Cannabis based products are available from wholesalers approved by the Commonwealth Office of Drug Control (ODC). Details of manufacturers and wholesale suppliers are available on the ODC website.
- For unregistered medicinal cannabis products, the pharmacy will need to provide the wholesaler with a copy of the TGA approval (SAS or AP documentation), before the wholesaler can release the product.
- Prescribers will usually provide a copy of the TGA approval to the patient with their prescription. If it is not provided, the pharmacist will need to contact the prescriber for a copy of the TGA approval.
- Alternatively, pharmacists may use the SAS/AP submission validation to verify TGA approval status in real-time. This tool displays the submission status and relevant details. If the search does not return any results, the prescriber should be contacted. A submission number is required to use the tool; contact the prescriber if it is not included with the prescription. For further information: SAS and AP Online System Information.
- Note: the TGA approval maintains the patient's privacy by only using patient initials.
- If the prescriber has provided the patient's WA Health approval, it must not be sent to the wholesaler as it includes the patient's identity. Similarly, wholesalers should not be provided with a copy of the prescription.
- The WA Medicines and Poisons legislation does not preclude a pharmacist from ordering any amounts of S4 or S8 medicines, including medicinal cannabis. However, as most cannabis-based products are not on the ARTG and therefore subject to alternative supply pathways, a copy of the TGA approval (SAS or AP) is required to be provided to the wholesaler before the product can be released. Pharmacists should check with the TGA and/or their wholesaler about their policy on ordering an unregistered product in anticipation of receiving prescriptions for dispensing.

Storage and record keeping

- Pharmacies are required to store cannabis-based products and maintain records in the same way as other S4 and S8 medicines.

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