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AMCA
Australian
Medicinal Cannabis Association

Proposal to remove Schedule 8 permit requirements for Schedule 8 medicinal cannabis (Vic)

Introduction

Access to medicinal cannabis has been legalised federally since 2016. While legalisation of medicinal cannabis by the Australian Federal Government was a major step forward, there are still a number of regulatory barriers and restrictions amongst the states and territories which undermine access.

Current State of the Regulatory Regime in Victoria

Access to medicinal cannabis in Victoria is regulated by both Commonwealth and State legislation. These include the *Therapeutic Goods Act 1989* (**'TG Act'**), the *Drugs, Poisons and Controlled Substances Act 1981* ('**Act'**) and the *Drugs, Poisons and Controlled Substances Regulations 2017* ('**The Regulations'**). In Victoria, under the Act, most medicinal cannabis products are categorised as "Schedule 8 Poisons" and must be dealt with under the regulations as such.

Practically, before a medical professional can prescribe medicinal cannabis products, they must obtain approval from the Therapeutic Goods Administration (TGA) and the State Health Department. Most medicinal cannabis products do not appear on the Australian Register for Therapeutic Goods (ARTG), however, the TGA has created mechanisms for medical professionals to still be able to prescribe medicinal cannabis where medically appropriate.

A registered medical practitioner seeking to prescribe medicinal cannabis may currently obtain access through the Special Access Scheme (**SAS**) or the Authorised Prescriber Scheme (**APS**). The SAS authorises medicinal cannabis prescribing for a single patient whereas the Authorised Prescriber Scheme allows registered medical practitioners to prescribe to multiple patients that present with similar clinical indications (i.e. a class of patients).

In addition to approval under the SAS or Authorised Prescriber Scheme, a Victorian registered medical practitioner must also obtain State approval to prescribe medicinal cannabis via a Schedule 8 Permit.

Proposed Changes

The Victorian Department of Health has proposed to remove Schedule 8 permit requirements for registered medical practitioners looking to prescribe to Schedule 8 medicinal cannabis for non-drug dependent patients. Specifically, the proposal would remove the definition of Schedule 8 cannabis and Schedule 8 tetrahydrocannabinol as special Schedule 8 poisons in the Regulations and thereby remove them from the special Schedule 8 permit requirements under Regulations 10, 11 and 12.

This change would still leave the safeguards of needing TGA approval and the use of the new SafeScript program in place to balance the ease of prescribing with proper safety nets. There will be no changes to permit requirements for drug-dependent patients, and prescribers would have to check SafeScript each time before prescribing a medicinal cannabis product.

AMCA Response to Proposed Changes

AMCA strongly supports the proposal to remove Schedule 8 permit requirements for registered medical practitioners who wish to prescribe Schedule 8 medicinal cannabis to non-drug dependent patients.

Each of the questions raised by the Department is addressed specifically below

Whether AMCA supports the removal of Schedule 8 permits for treatment with Schedule 8 medicinal cannabis for non-drug dependent patients?

AMCA supports the proposed removal of Schedule 8 Permits for treatment with Schedule 8 medicinal cannabis for non-drug dependent patients.

Whether AMCA considers that this regulatory reduction may have a negative impact for patient outcomes or prescribers

AMCA does not consider that the proposed regulatory changes will have a negative impact for patient outcomes or prescribers. On the contrary, the AMCA believes that the removal of the requirement for S8 permits for the treatment of non-drug-dependent patients will ease the administrative burden on both physicians and the Department, and will avoid unnecessary delays in patients being able to access treatments. This is likely to lead to better patient outcomes, as patients who would be deemed by their medical practitioner to clinically benefit from medicinal cannabis would be able to obtain access medicinal cannabis without the extra layer of state regulation, noting that the clinical justification for treatment would already have been established through the Federal approval under the SAS and APS.

Overall, easing the regulatory burden on both prescribers and patients will facilitate access to medicinal cannabis and would rely on the approvals under the Federal access schemes as providing sufficient clinical justification for the prescribing. Further, access to SafeScript will provide prescribers and pharmacists with real-time information about a patient's history with respect to high-risk medicines (such as medicinal cannabis), which will provide valuable information to the medical practitioner about whether prescribing of medicinal cannabis to that patient is appropriate having regard to their history.

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