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SUBMISSION

Wednesday, 12 March 2025

AMA submission to the TGA's targeted consultation for the institution of legal provisions to share special access scheme information

Consultation closes 12 Mar 2025

By email: SAS.Support@health.gov.au

Introduction

The Australian Medical Association (AMA) is broadly supportive of the Therapeutic Goods Association's (TGA) proposed legislative instrument to enable the sharing of information with other regulators relating to therapeutic goods accessed via the unapproved therapeutic goods framework. The instrument should make it easier for regulators to address the exploitation of the Special Access Scheme (SAS) and the Authorised Prescriber Scheme (APS), predominantly perpetrated by vertically integrated, direct-to-consumer telehealth entities.

AMA members have been appalled by the behaviour of some of these entities, most notably in the dispensing of medicinal cannabis. We have raised this as an issue to the TGA and other regulators, including the Australian Health Practitioner Registration Agency (Ahpra) and the Medical Board of Australia. While we are supportive of the change in this consultation, the issue will require more significant reforms from the TGA, which we detail later in the submission.

Position on SAS and APS

The only appropriate prescription for unapproved medicines is that which takes place in the context of the broader health assessment and medical expertise provided by a patient's usual medical practitioner.

Accordingly, the AMA prefers therapeutic goods supplied in Australia to be registered through the Australian Register of Therapeutic Goods (ARTG) so they are adequately assessed for quality, safety, and efficacy. The AMA believes unapproved therapeutic goods should only be used in very limited circumstances. When they are used, alternative methods of regulation such as those under Therapeutic Goods Orders should be similar to ARTG regulation and highly restrictive to ensure patient quality and safety.

Measures such as the SAS and the APS are sensible approaches to providing access to certain relatively low-risk, unapproved therapeutic goods in cases where a patient is seriously ill, or the prescribing practitioner resides on an established history of use list. These circumstances permit

urgent and rapid access to an unapproved therapeutic good when deemed clinically necessary, supported by a clear notifications process.

The AMA has supported measures to streamline the application process under the AP scheme (Categories A and C) in the past, to reduce the administrative burden on medical practitioners, and for those instances where it is appropriate to reduce the access time for patients where possible.

This is appropriate when it is deemed clinically necessary by medical practitioners, and this should always be the guiding rationale for providing patients access to unapproved therapeutic goods. Access to medicines and medicine scheduling must consider pharmacology and toxicology, but also how the medicines in question are being used in clinical practice.

It is therefore beneficial to the system broadly, if practitioner prescribing habits and trends are shared with regulatory bodies to inform ongoing improvements to support enhanced patient safety.

Do you agree with the introduction of a legislative instrument for the TGA to share information relating to unapproved therapeutic goods accessed by health practitioners with Ahpra and/or State and Territory Governments? Justification

The AMA is supportive of a robust regulatory scheme with medicines regulated by the TGA and practitioner behaviour regulated by Ahpra and the relevant national board.

The proposed instrument would likely enhance patient safety and prescribing practices by identifying and addressing questionable behaviours, ensuring better oversight, and supporting informed regulatory actions. However, while this collaboration could contribute to higher quality practices, the accountability it seeks to impose must be proportional to clinical risk and respectful of practitioner's clinical judgement.

The TGA has no role in regulating health professional behaviour and this must not change. However, it is reasonable to expect that a practitioner applying to provide patients with access to unapproved therapeutic goods would be subject to additional scrutiny, and that the TGA can share relevant information with the appropriate regulator when there is genuine concern with their behaviour.

Examples in the consultation paper include a medical prescriber treating more than 31,000 patients with medicinal cannabis within six months, a nurse practitioner submitting applications for medicinal cannabis despite being subject to prescribing restrictions, and a pharmacist submitting high volumes of nicotine vaping products. The AMA supports relevant information for cases like these being shared with Ahpra.

The rapid increase in the prescription of unapproved medicinal cannabis products[1] remains a serious concern for the AMA. The AMA has made multiple representations to the TGA and to relevant health ministers advocating for improved regulatory controls and standards for medicinal cannabis products and associated tetrahydrocannabinol (THC) concentrations. This is an instance where the TGA is informed of troubling prescribing trends and habits. The TGA should have the power to share this

[1] https://www.nps.org.au/news/medicinal-cannabis-access-pathways-faqs-for-prescribers

information with Ahpra and the state/territory governments to action reforms to enact more appropriate regulation.

Would having the ability to request the information contained in (TABLE 1) be of assistance for the operations for your agency's functions? Justification

The AMA would not be a requesting body for the information contained in Table 1. However, we strongly recommend it is made clear to everyone involved that their personal information may be shared. This includes: the submitter, the treating practitioner, the Human Research Ethics Committee (HREC), and the patients.

While the information they are disclosing about patients (initials, date of birth, gender, treating doctor, and drug) is not identifiable, it will be "personal information" if Ahpra or state/territory recipients have other information that will identify the patient.

Additional reforms

The AMA is disappointed and frustrated by the exploitation of the SAS and APS, particularly by the medicinal cannabis industry. One of the AMA's great frustrations is the amount of time and effort the TGA and stakeholders like the AMA spend trying to ensure a minimum safety and quality framework for products like medicinal cannabis and vapes because they refuse to engage with our established regulatory processes. Medicinal cannabis clinics continue to flagrantly breach the TGA's guidelines,[2] and AMA members are increasingly reporting serious adverse outcomes for patients.

Beyond this consultation we recommend the TGA considers reforms to how unapproved medicinal cannabis products are accessed in Australia. This should begin with a review of the categories of medicinal cannabis products, and the complete removal of category 5 — products with a THC content greater than 98 per cent — while the review is conducted. There is no reasonable justification for medicinal cannabis products to contain such a high percentage of THC, yet we understand it is the most frequently prescribed of the categories.

As previously stated, the AMA prefers therapeutic goods to be registered on the ARTG. To ensure the SAS is not used as a loophole to avoid registering on the ARTG, the TGA should consider reforms that would limit the quantity of products accessed through a SAS before it has to register on the ARTG or lose access through the SAS or APS. If a specific product or category of products reaches a certain level, companies producing these products should be required to explain why they have not applied for the product to be registered on the ARTG. If they cannot provide a satisfactory reason, the products should be excluded from the SAS or APS.

The benefit of this approach would be that it would ensure the legitimate use of SAS would be uninterrupted.

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[2] https://journals.sagepub.com/doi/10.1177/00048674241307158