RACGP Victoria

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Legislative and Regulatory Reform Team
Regulatory Reform and Policy Branch
Health Regulator | Corporate Strategy and Operations
Department of Health

Re: Discussion paper for the Drugs, Poisons and Controlled Substances Regulations 2017 review

The Royal Australian College of General Practitioners (RACGP) Victoria thanks the Department of Health for the opportunity to provide feedback on the *Drugs, Poisons and Controlled Substances Regulations 2017* (the Regulations) sunset review Discussion Paper.

The RACGP is the voice of specialist general practitioners (GPs) across Australia, representing more than 50,000 members, with over 10,000 in Victoria. Every year, more than 22 million Australians choose to visit a specialist GP for their healthcare needs, making GPs the most accessed health professional in the country.

GPs play a central role in the continuum of alcohol and other drug (AOD) care, from prevention and early detection to treatment, recovery and long-term support. Specialist GPs also play a key role in prescribing and managing scheduled medicines as part of holistic patient-centred care. RACGP Victoria supports the Department's objective to ensure the Regulations remain effective, proportionate, and responsive to current risks and clinical practice. We also acknowledge the role of SafeScript in supporting safer prescribing and reducing harm associated with high-risk medicines.

However, our members report continued issues with SafeScript, including gaps in information, access and integration issues, as well as ongoing concerns about punitive approaches to enforcement rather than educative.

Our feedback on the draft Discussion Paper and proposed areas for reform follows:

2. Refining real time prescription monitoring reforms

Any reforms to SafeScript should be based on the following principles:

- it should improve patient safety, without increasing red tape and the administrative burden on GP consultations
- it is reasonable for practitioners to check SafeScript in most circumstances, but the process should be seamless for GPs, and must not be so time consuming as to reduce access to care
- recognise and apply exemptions for lower risk settings, such as people in residential aged care where medicines are registered to patients and pharmacists provide medication governance
- there must also be national consistency, especially for cross-border settings
- increased regulatory requirements should not create unnecessary legal risk for GPs as this will create barriers to care for patients
- all practitioners who prescribe Schedule 8 medicines should be required to check SafeScript.
- where SafeScript identifies problematic prescribing at individual practitioner levels, RACGP recommends targeted education of those individuals rather than the application of additional system wide reforms that burdens compliant prescribers unnecessarily

2.1 Requiring a prescription for medicinal cannabis

The RACGP supports the inclusion of medicinal cannabis in SafeScript to promote safer use and strengthen oversight.

The RACGP has called for reforms to the way medicinal cannabis is prescribed, including a requirement for all products to be approved on the Australian Register of Therapeutic Goods (ARTG).

2.2 Appropriate actions to be taken after checking SafeScript

We do not support the proposed requirement for action from prescribers, when a SafeScript check for a patient shows recent prescribing of the same or similar monitored poisons by previous practitioners.

Our members have told us that the proposed requirement to contact other prescribers in SafeScript, and document those efforts if unsuccessful, is not workable in a consultation and routine care settings. This represents an unreasonable legal and administrative impost on GPs for which no remuneration is available.

There is significant concern this would not operate as a clinically meaningful safeguard.

This proposal operates under the assumption that multiple prescribers necessarily indicate inherent clinical risk. The majority of patients with multiple prescribers are receiving care from legitimately collaborative teams, particularly post-operative and post-discharge management.

There is a significant risk that additional administrative requirements will incentivise GPs to disengage from prescribing controlled substances, divert patients requiring those substances into public health services and negatively impact Victoria's efforts to increase the workforce capacity in drug and alcohol medicine, pain management and palliative care.

RACGP Victoria also notes concerns regarding inconsistencies in regulatory approaches across medicines, including the level of permitting required for buprenorphine despite its comparatively favourable safety profile. Consideration should be given to whether current permitting requirements remain proportionate to risk, particularly in the context of mandatory SafeScript use.

Current regulatory settings may also inadvertently reinforce stigma, including through the designation of "drug dependent person", which can create barriers to appropriate prescribing. Consideration should be given to approaches that reduce stigma and support timely, clinically appropriate care.

4. Permissions for specified persons

4.1 Registered paramedics to possess and administer in broader health services

Registered paramedics have a well-established, regulated role in the possession and administration of medicines within emergency care settings, operating under defined clinical protocols and organisational governance arrangements. Any extension of authority for registered paramedics to to possess and/or administer Schedule 4 and Schedule 8 medicines beyond or outside of emergency settings should be approached cautiously and only within formally integrated, multidisciplinary models of care.

Such arrangements must be supported by clear medical oversight, robust clinical governance frameworks, and well-defined scopes of practice aligned with state and territory regulatory requirements. In primary care and other

community-based settings, the safe use of medicines by paramedics would require clearly articulated clinical protocols, reliable and comprehensive documentation and handover processes, and explicit escalation pathways to a general practitioner. These safeguards are particularly important where medicine administration may initiate, alter or extend ongoing clinical management. To support continuity of care and minimise the risk of fragmented or episodic treatment, timely communication with the patient's usual GP - where one exists and with patient consent – should be a core expectation. Documented follow-up arrangements and shared clinical responsibility are essential to ensuring patient safety and high-quality care beyond the initial episode. Poorly integrated multidisciplinary care risks fragmenting relational continuity, even when clinically competent.

RACGP response to general questions

RACGP Victoria provides the following responses to the general questions outlined in the Discussion Paper.

What works well in the current Regulations?
RACGP Victoria supports the current ability to prescribe ongoing opioids at oral morphine equivalent doses (OMEDs) under 100mg without requiring a permit, which supports timely and appropriate patient care. The integration of Schedule 2 permit applications within SafeScript is also positive, allowing prescribing and permit processes to occur within the same system.

What does not work well in the current Regulations?

Several aspects of the current regulatory framework present challenges in practice. Dosing and dispensing documentation for opioid replacement therapy (ORT) can be unclear, including limited visibility of last dosing, and PBS prescribing information may not be updated in real time, impacting clinical decision-making.

There are also concerns regarding the inability to remove the designation of "drug dependent person", which may contribute to stigma and create barriers to appropriate prescribing, including for acute pain management. Mechanisms are needed to support timely, clinically appropriate care for patients receiving ORT.

If the Regulations reflected best practice, how would we know?

Best practice regulatory settings would support a reduction in stigma for patients seeking care for drug dependence, reduce harm associated with overdoses and polysubstance use, and improve patient outcomes. This would include better identification of patients at risk and improved access to referral pathways for appropriate treatment and support.

What is the one change that would make the biggest improvement?

RACGP Victoria considers the most significant improvement would be recognising a SafeScript "green tick" within clinical software as a valid record of checking, reducing duplication and administrative burden while maintaining patient safety. SafeScript should function as a clinical decision-support tool, rather than primarily a compliance mechanism. Evidence from Australia and internationally indicates that real-time prescription monitoring systems are most effective when combined with investment in community-based alcohol and other drug treatment services (see Australian Prescriber article and international evidence).

While the RACGP supports the intent of the proposed reforms to improve patient safety, it is essential that any changes are aligned with the realities of general practice, and do not increase the administrative and compliance burden on GPs. We also strongly call for an educative approach, rather than punitive, and avoiding any changes that create legal risk for GPs which can result in reduced access to care for patients.

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We welcome further consultation and collaboration with the Legislative and Regulatory Reform on the review and reform of the Drugs, Poisons and Controlled Substances Regulations (2017).

Yours sincerely

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