



Submission to the Therapeutic Goods Administration Consultation
on

Prescription strong (Schedule 8) opioid use and
misuse in Australia – options for a regulatory
response



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ABOUT RDAA

RDAA is the peak national body representing the interests of doctors working in rural and remote areas and the patients and communities they serve.

RDAA's vision for rural and remote communities is simple – excellent medical care.

This means high quality health services that are:

- patient-centred
- continuous
- comprehensive
- collaborative
- coordinated
- cohesive, and
- accessible

and are provided by a GP-led team of doctors and other health professionals who have the necessary training and skills to meet the needs of their communities.

CONTACT FOR RDAA

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INTRODUCTION

The Rural Doctors Association of Australia (RDAA) recognises that misuse of prescribed opioids is becoming increasingly problematic in Australia. RDAA believes that the issue is of significant concern, and welcomes the opportunity to provide feedback to the Therapeutic Goods Administration (TGA) consultation on *Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response*.

RDAA notes that there are economic and political complexities within the current health environment that are impacting on responses to this trend. These include the recent up-scheduling of codeine which has generated significant “white noise” that may impact on any new strategies directed toward reducing the prescription and use of opioids and the General Practitioner Opioid Prescribing compliance strategy currently being developed by the Commonwealth Department of Health. Strategic, legislative and regulatory responses must be aligned to give the best chance of successfully minimising the misuse of opioids.

RDAA also emphasises that while value for the health dollar must be considered, improved patient outcomes should be the most important driver of health system activity. **In particular, before any changes to regulatory frameworks are implemented, the challenges in providing high quality health care in rural and remote Australia must be recognised and addressed.** In these areas the degree of remoteness and other geographic, climatic, socio-economic, demographic and cultural factors impact on the delivery and cost of health services and, consequently, significant inequities of access to health professionals and services and poorer health outcomes persist.

This requires that policy makers and regulators work with clinicians to align strategic and regulatory responses, develop common understandings and provide a legislative and regulatory framework that is underpinned by solid clinical evidence. Any related standards, guidelines, indicators, processes and requirements, must also be developed using a rural and remote lens. They must be developed with appropriate rural and remote stakeholder input and with the clear understanding that the availability of human, physical and capital resources in rural and remote communities is variable.

RDAA has identified some key issues for consideration.

KEY ISSUES

Clinical practice must be supported by a national approach to opioid prescribing to ensure patients receive high quality and safe care.

An alignment of strategic, legislative and regulatory responses underpinned by clinical evidence is necessary to ensure the use of best practice approaches to opioid prescription and give initiatives aimed at minimising the misuse of opioids the best chance of success. Interrogation of data to reflect geographical variations is necessary to appropriately target responses.


Cross-border prescribing or sourcing could also become increasingly problematic without this national approach. It should include effective real time monitoring solutions.

Restricting prescribing to specialist/authority prescribing will negatively impact on rural and remote patients.

RDAA has significant concerns with *Option 3: Consider whether the highest dose products should remain on the market, or be restricted to specialist/authority prescribing*. Restricting prescribing to specialist/authority prescribing may have significant adverse effects on rural and remote patients.

Access to specialists and specialist clinics – including for pain management, substance dependence management or withdrawal and palliative care – is a major problem in many parts of rural and remote Australia. The distances and cost of travel both in terms of dollars for transport (even using available patient transfer schemes) and accommodation, and in the time that rural and remote Australians incur for face-to-face specialist treatment, exacerbate the impact of this poor access. The impact of time away from work and from family and community places additional stress on their mental and physical health. There are also significant access issues when seeking remote advice or review from specialists.

This type of strategy is indicative of metro-centric approaches to solving issues. Rural and remote GPs cannot, for example, arrange a lengthy patient transfer on possibly poor roads for a palliative care patient requiring analgesia for metastatic cancer pain. They must be supported to provide such care close to home.



Rural and remote GPs should also be provided with support to adopt a rehabilitative role in cases of withdrawal from opioids.

The provision of appropriate and supported access to education and training on the use and prescribing of opioids for rural and remote doctors is essential.

RDAA acknowledges the increasing evidence against the use of opioids for chronic non-cancer pain. It is critical therefore that appropriate and supported access to education and training that reflects the changes in evidence, and improves understandings of clinical indicators and what constitutes best clinical practice in relation to the prescribing of opioids and alternatives, is made available to rural and remote GPs.

The TGA should work with rural and remote doctors, their representative organisations and relevant medical Colleges to develop and disseminate clear guidelines about appropriate use and to identify and provide options for up-skilling. The establishment of a National Rural Generalist Pathway will offer the opportunity to deliver Advanced Skills Training for doctors in specialties needed in their communities. This opportunity should be explored for addiction medicine, pain management and palliative care.

Any proposed changes to legislative and regulatory changes governing opioids, including changes to prescribing, require an appropriate timeframe for implementation.

Timeframes for any changes to legislation, regulation and associated processes must recognise that addressing the specific challenges around opioids (as they are used both licitly and illicitly) necessitate careful planning to align and implement responses.

It is important that sufficient time be allocated to information dissemination and the education and training of both prescribers and consumers.