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

Thank you for the opportunity to provide input into the Therapeutic Goods Administration (TGA) consultation on a regulatory response to the potential misuse of prescribed Schedule 8 (S8) opioids in Australia.

Avant is Australia's largest medical defence organisation, providing professional indemnity insurance and legal advice and assistance to more than 75,000 healthcare practitioners and students around Australia.

In addition to assisting members in claims and complaints under our insurance policies, Avant regularly provides members with advice, information, education and support around prescribing S8 drugs. Our experience is that patients and practitioners are at risk due to confusion surrounding the prescription of S8 drugs.

In assisting our members with professional conduct claims, coronial inquiries and civil proceedings, we see the impact of inadequate regulation around S8 drugs. Many practitioners face challenges dealing with patients who are drug-dependent or drug-seeking. This can lead to inappropriate prescribing to patients who should not receive drugs of dependence and inappropriate non-prescribing to patients who should receive them.

Avant has supported and called for measures which change prescribing behaviour, including:

- the implementation of a national real-time monitoring system
- the development of clinical support tools within clinical information systems to support doctors at the point of prescribing
- national harmonisation of legislation and regulation (including consistent terminology and clear definitions)
- continued and further education and guidelines about the legal and clinical aspects of prescribing S8 drugs.

Our position paper [Prescribing drugs of dependence](#) is attached for your information.

Our comments in relation to the consultation paper are below.

1. Avant agrees that regulation can play an important role in underpinning appropriate use and minimising misuse of S8 drugs.

2. Avant is supportive of the following regulatory options proposed in the consultation paper:
 - a. Option 1 - Reducing the pack size of S8 opioids.
 - b. Option 2 - Reviewing the indications for strong opioids by the TGA and amending product information in line with that review.
 - c. Option 5 - Reviewing (and inserting) warnings on labels and revising consumer medicines information.
 - d. Option 6 - Prioritising the review of new chemical entities for pain relief and opioid antidotes.
 - e. Option 7 - Potential changes to the use of appendices in the Poisons Standard to provide additional regulatory controls for strong opioids.
 - f. Option 8 – Increased education about the alternatives to opioids (both Schedule 4 and S8) in the management of chronic pain.

3. In relation to option 3, our concern is primarily around any proposal to restrict prescribing to specialists. General practitioners are an integral part of the treatment team for chronic and complex patients. Specialists, including pain specialists, may not always be available and/or accessible to all patients. A restriction on non-specialist prescribing may pose particular challenges to patients (particularly cancer patients), and we agree that the impacts and cost under this option need to be carefully considered.

We suggest further consideration of this option, including the role that the Pharmaceutical Benefits Scheme (PBS) could play in imposing restrictions, as noted in the consultation paper.

We are not qualified to make any comment about whether high dose S8 products should remain on the market.

4. In relation to option 4, we support the strengthening of risk management plans for opioid products to ensure best practice is reflected in prescribing and management of risks. As far as topics for education (referred to on page 16 of the consultation paper), we suggest strategies for managing patient expectations (at the individual practitioner and practice level) should also be included.

Care should be taken with developing prescriptive guidelines as patients' needs and situations vary. Any guidelines should be sufficiently flexible to permit the exercise of clinical judgement.

Please contact me on the details below if you require any further information or clarification of the matters raised in this submission.

Yours sincerely



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