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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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Avant Position Paper

Prescribing drugs of dependence

Prescribing drugs of dependence

Patients and practitioners are at risk due to the confusion surrounding prescription of drugs of dependence.

Avant calls for the implementation and evaluation of a national real-time prescription monitoring system as a matter of urgency.

Avant supports:

- ▶ Development of clinical decision support tools within clinical information systems to support doctors' decision making and adherence to regulations.
- ▶ Harmonisation of relevant legislation and regulation (including consistent terminology and clear definitions) around Australia for prescribing drugs of dependence.
- ▶ Continued and further education and guidelines for doctors about the legal and clinical aspects of prescribing drugs of dependence.

Avant believes that changes to the way drugs of dependence are regulated, monitored and prescribed would ensure their safe and effective use and allow:

- ▶ better coordination between various states and authorities
- ▶ an improved ability to monitor and track dispensing data to a better defined cohort of patients
- ▶ the ability to educate doctors about the legislative requirements at a national level
- ▶ a reduction in harms to patients.

April 2015

Background

In Australia, all medications are classified through the process of scheduling to ensure their safe and effective use. Each state and territory has their own legislation but it adheres closely to the Standard for the Uniform Scheduling of Drugs and Poisons.¹

Prescription of Schedule 8 drugs (S8) is heavily regulated as they are substances which have a higher risk of abuse, misuse and the potential development of dependence. Opioid analgesics (opioids) fall into the S8 category.

Similarly, some Schedule 4 drugs (S4) have a risk of misuse, abuse or are liable to cause dependence and are also subject to special requirements. For example, most benzodiazepines are S4 drugs, whereas some are classified as S8 drugs.

The term “drugs of dependence”² encompasses all S8 drugs and specified S4 drugs which are open to misuse, abuse, trafficking and liable to cause dependence.

Research identifies a consistent and substantial increase in the prescription of opioids in Australia.³ Between 1992 and 2012, opioid dispensing increased 15-fold and may be attributed to the increasing prevalence of chronic pain (particularly in the elderly), as well as the increasing availability and approved indications of various opioids.⁴ Avant is concerned at the emerging evidence of a corresponding increase in opioid related harm, including hospitalisations and deaths where they were a contributing factor.

Avant’s Medico-legal Advisory Service (MLAS) provides support and advice to members when they encounter medico-legal issues. There has been an increase in the number of calls made to the MLAS and an increase in claims where drugs of dependence were involved.

Recent decisions handed down by coroners in Victoria and New South Wales have repeatedly recommended changes to the way drugs of dependence are prescribed, monitored and regulated.⁵

The Coroners Court of Victoria highlights the contribution of medication in deaths. Figures released in 2013 by the court demonstrate 82.8% of drug-related deaths in Victoria were due to prescription drugs with opioid analgesics and benzodiazepines the top contributing medication groups.⁶

Avant's experience

Avant is Australia's leading medical defence organisation (MDO) representing more than 64,000 healthcare practitioners and students.

In assisting medical practitioners to respond to notifications and complaints, Avant sees first-hand the impact of the regulations that surround drugs of dependence.

In Avant's experience, the majority of matters related to drugs of dependence involve GPs who are at the front line of prescribing opioids.

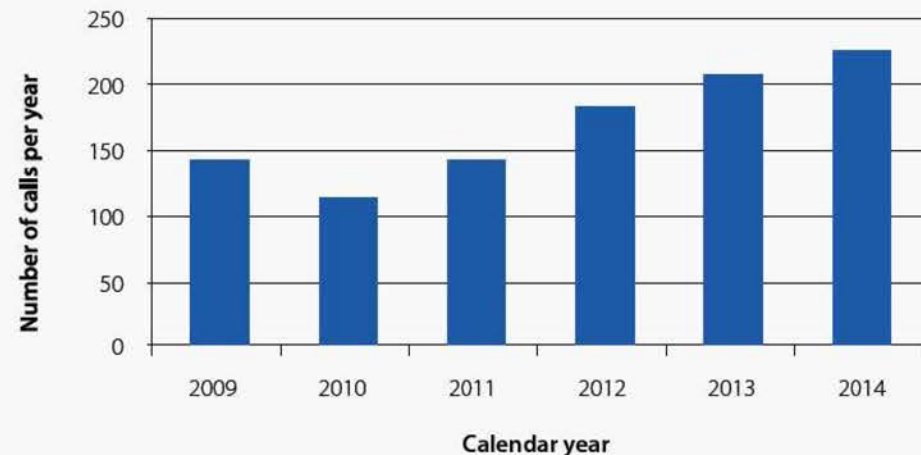
Many medical practitioners face challenges dealing with patients who are drug dependent or drug seeking. This can lead to inappropriate prescribing to patients who should not receive drugs of dependence, and inappropriate non-prescribing to patients who should receive them.

Medico-legal Advisory Service

Between 2009 and 2014, Avant's MLAS received over 1000 requests for advice where drugs of dependence were a key item of concern. There has been an increase in the number of calls over this period, which shows that this is a growing issue of concern for our members.

MLAS calls focused on clarifying if an authority was required to prescribe a drug of dependence. This indicates that many doctors may still be unaware of or do not completely understand their legal obligations around prescribing drugs of dependence.

Figure 1: Number of MLAS calls about drugs of dependence – 2009-2014



Claims

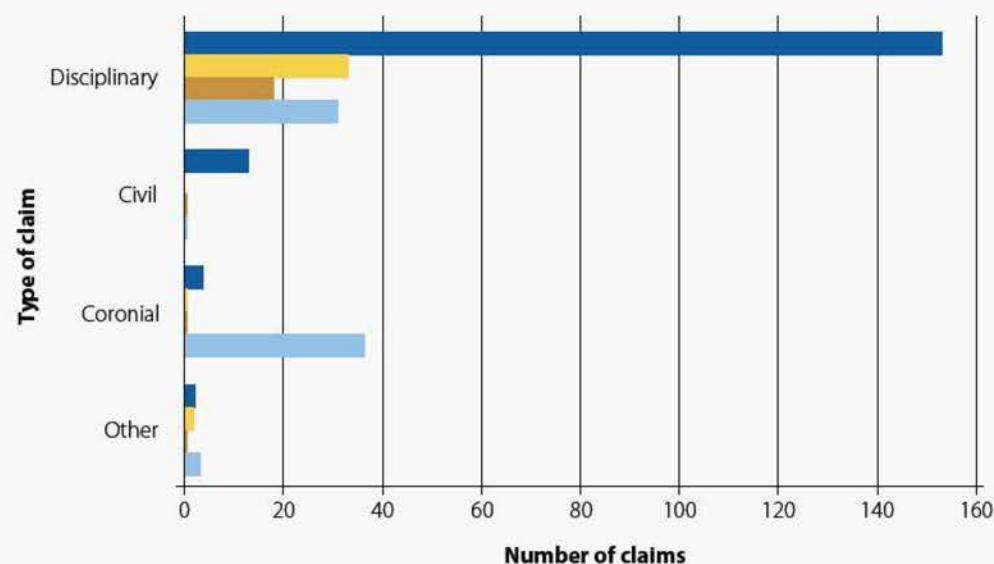
During this same period, Avant assisted our members in over 230 claims identified as being related to drugs of dependence.

Analysis of Avant claims data between 2009 and 2014 showed that the majority of claims had multiple reasons per claim (total of 302 reasons identified). For example, one claim may have arisen due to a request from the coroner and an allegation of inappropriate prescribing. The most common factors include:

- ▶ alleged inappropriate prescribing, including "over-prescribing", was identified in 73.5% of claims identified as being related to drugs of dependence
- ▶ alleged prescribing without authority (15.4%)
- ▶ alleged refusal or cessation of prescription (9%)
- ▶ request for information or a statement (31.2%) came from multiple sources such as:
 - coroners and police for use in coronial matters
 - state or territory government bodies e.g. Department of Health
 - complaints body or a medical board
 - solicitors.

In Avant's experience, the majority of claims related to drugs of dependence arose in disciplinary matters.

Figure 2: Number of reasons identified involving involving drugs of dependence by type of claim⁷ and issue – 2009-2014



Analysis and recommendations

Real-time prescription monitoring

Avant believes that a national real-time prescription monitoring system will enable practitioners to have the benefit of the complete clinical picture when prescribing drugs of dependence. This system will go towards supporting the safety of patients and minimising the risk of doctor shopping for the purpose of drug diversion or on-selling.

In 2014, Coroner Heffey stated there is now a long list of coronial recommendations repeatedly urging the implementation of a real-time prescription monitoring system in Victoria.⁸ Such a system has been recommended seven times since 2012 in Victoria.⁹

This call has been repeated in New South Wales with Deputy State Coroner Forbes recommending a real-time web-based monitoring program be made available to pharmacists and general practitioners.¹⁰

Similar recommendations for a national database and a national computerised pharmacy system have been put forward by coroners in Queensland.¹¹

Avant supports calls for a national real-time prescription monitoring system to be implemented and evaluated as a matter of urgency. The system must be computerised, operate in real-time and be national in coverage.

In addition, Avant believes that clinical information systems could be utilised to support practitioners' decision making at the point of prescribing drugs of dependence. These tools would also increase doctors' awareness of state-based regulation by providing prompts and links to the relevant regulations and guidelines.

Legislation and regulation

The legislation around Australia that applies to drugs of dependence is inconsistent as each state and territory has their own legislation controlling the storage, prescribing, and dispensing of drugs. This is in contrast to the Pharmaceutical Benefits Services (PBS), which is a Commonwealth scheme that applies nationally.

In Avant's view, this causes confusion amongst practitioners about their legal obligations and puts patients and practitioners at risk. Avant supports the harmonisation of legislation around Australia for prescribing drugs of dependence. Avant also supports the development and use of consistent terminology as a matter of priority.

For example, there are seven different terms that are used to classify S8 drugs in different state and territory legislation:

- ▶ "controlled medicine"
- ▶ "drug of addiction"
- ▶ "S8 poisons"
- ▶ "controlled drug"
- ▶ "narcotic substance"
- ▶ "drug of dependence"
- ▶ "S8 substance".

State and territory requirements vary as to the circumstances in which practitioners are required to obtain approval to prescribe a drug of dependence from the relevant authority. Generally, approval and/or notification is required when it is to be prescribed for longer than two months or the patient is "drug dependent".

The definition of "drug dependence" varies from state to state. Some legislation concentrates on the psychological and drug seeking behaviour of the patient, which concords to some extent with clinical definitions.

Avant believes there should be a clear, unambiguous and nationally consistent definition of drug dependency in the legislation which will make it clear when practitioners require approval.

Education and guidelines

Twenty one per cent of disciplinary cases for professional misconduct of doctors in Australia and New Zealand involved illegal or unethical prescribing as the primary issue.¹²

Avant believes that there should be more education for doctors about the legal and clinical aspects of prescribing drugs of dependence, which may go towards reducing the number of disciplinary cases involving inappropriate prescribing.

In Avant's experience, many practitioners have little knowledge of their legal obligations around prescribing drugs of dependence and the regulations applicable in their state. In our view, there is also confusion amongst practitioners over the role of the PBS in providing authority to prescribe certain medications.

For example, in Victoria an authority must be obtained from the Department of Health when prescribing specific drugs of dependence for longer than two months; this is distinct from obtaining an "authority" from the PBS.

Recent decisions handed down by coroners also recommend better prescribing guidelines for practitioners.¹³

In Victoria, Coroner Jamieson further noted that GPs might benefit from better education in dealing with complex and difficult patients and substance abusers.¹⁴

Mutual trust and building rapport are fundamental principles of the doctor–patient relationship. Avant believes these principles, when coupled with a lack of education, contribute to many doctors finding it hard to assess and decline a patient's request for drugs of dependence.¹⁵

Further and continued education for practitioners about the legal and clinical aspects of prescribing drugs of dependence will ensure their safe and effective use. This education should be multifaceted, and emanate from many sources including Avant, colleges, guidelines, state health departments and their respective pharmaceutical services units.

Avant's position

Patients and practitioners are at risk due to the confusion surrounding prescription of drugs of dependence.

Avant calls for the implementation and evaluation of a national real-time prescription monitoring system as a matter of urgency.

Avant supports:

- ▶ Development of clinical decision support tools within clinical information systems to support doctors' decision making and adherence to regulations.
- ▶ Harmonisation of relevant legislation and regulation (including consistent terminology and clear definitions) around Australia for prescribing drugs of dependence.
- ▶ Continued and further education and guidelines for doctors about the legal and clinical aspects of prescribing drugs of dependence.

Avant believes that changes to the way drugs of dependence are regulated, monitored and prescribed would ensure their safe and effective use and allow:

- ▶ better coordination between various states and authorities
- ▶ an improved ability to monitor and track dispensing data to a better defined cohort of patients
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- ▶ a reduction in harms to patients.

Key links

- ▶ Avant Risk IQ factsheet 'Prescribing drugs of dependence'
<http://www.avant.org.au/schedule8/>
- ▶ Avant Risk IQ webinar 'Doctor shoppers, the law and addiction: prescribing drugs of dependence'
<http://cpd.avant.org.au/course/view.php?id=13>

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5. Inquest into the Death of James 15 February 2012, Coroner Olle; Inquest into the Deaths of Christopher Salib, Nathan Attard and Shamsad Akhtar, 27 June 2014, Deputy State Coroner C Forbes.
6. Coroners Court of Victoria. Coroners Prevention Unit – Victorian Deaths and Acute Drug Toxicity – Yarra Drug and Health Forum (May 2013), <http://www.coronerscourt.vic.gov.au/resources/3c7fa964-bec2-4189-abb0-684f747aa6ec/cpu+-+ydhf+presentation+-+06may13+-+final+4+to+page.pdf>
7. Disciplinary claims refer to cover for legal fees and expenses for disciplinary proceedings and investigations; Civil claims refer to cover for the amounts a medical practitioner becomes legally liable to pay as compensation for civil liability, including legal defence costs; coronial claims refer to cover for legal fees and expenses for a coronial inquiry or inquest.
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