Pharmaceutical Society of Australia

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

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Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission to the Therapeutic Goods Administration (TGA) to provide comments on options for a regulatory response to the use and misuse of prescribed Schedule 8 (S8) opioids in Australia.

About PSA

PSA is the peak national professional pharmacy organisation representing Australia's 30,000 pharmacists[1] working in all sectors and locations.

PSA's core functions include:

- providing high quality continuing professional development, education and practice support to pharmacists
- developing and advocating standards and guidelines to inform and enhance pharmacists' practice
- representing pharmacists' role as frontline health professionals.

PSA is also a registered training organisation and offers qualifications including certificate and diploma-level courses tailored for pharmacists, pharmacy assistants and interns.

[1] Pharmacy Board of Australia. Registrant data. Reporting period: 1 October 2017 – 31 December 2017. At: www.pharmacyboard.gov.au/About/Statistics.aspx

Summary

PSA believes all of the options suggested in the consultation paper have merit and are, in fact, complementary. To help reduce harm in the use of opioids and improve their quality use, a holistic coordinated approach is recommended to appropriately address the needs of multiple stakeholders.

Please note that, given the options and possible solutions are interrelated, we have not provided specific recommendations for each option in this summary section.

We stress that, in developing a regulatory response, it is fundamentally important that access to evidence-based opioids continues to be supported.

PSA seeks to work in partnership with the Australian Government and other stakeholders to develop and disseminate professional practice support tools which will help enable a consistent response by prescribers and pharmacists. Education materials for patients and carers will also be vital as is having consistent key messages around the use and associated risks of opioids.

PSA re-iterates its position that a national real-time recording and reporting system is essential from a patient safety and public health perspective.

General comments

PSA welcomes the review of regulatory options relating to S8 opioids given the concerning trends of significant increase in use in Australia and internationally. PSA agrees with the statement in the consultation paper that "any regulatory response must not unduly restrict informed, rational prescribing of opioids".

Pain management is a complex health issue. Opioids are used in acute pain and malignant disease but the evidence base for use in chronic non-cancer pain is limited. Further, the need for opioids for pain management in life-limiting illnesses is not restricted to malignant disease. Specialist advice suggests, for example, that heart failure, renal failure or chronic obstructive pulmonary disease in their terminal phase also require opioids for pain relief.

PSA has considered each of the options presented in the consultation paper. We note that an option may be related to or associated with another option and the manner of implementation of these options may influence the overall outcome. PSA also notes that some of the options presented in this consultation paper have been canvassed[2] previously in the context of opioid

[2] National Drug and Alcohol Research Centre. A review of opioid prescribing in Tasmania: a blueprint for the future. Sydney: University of New South Wales; 2012. At: **https://ndarc.med.unsw.edu.au/sites/default/files/ndarc/resources/Tas%20Opioid%20Prescribing%20report%20final.pdf**

prescribing in Tasmania.

Overall, PSA believes that all of the options presented in the consultation paper have some merit. The complexity of the issue at hand means that a holistic approach is needed with multiple solutions likely to be necessary to target different problems or tailor initiatives for different stakeholders. In addition, even a comprehensive regulatory approach will only be meaningful if there is education for and good communication with prescribers, pharmacists and patients, and relevant practice support for health practitioners.

Comments on regulatory options

Option 1: Consider the pack sizes for S8 opioids

Require sponsors to register and make available for supply both smaller (such as maximum three-day) pack sizes for treatment of patients with acute pain and suitable pack sizes (14 or 28-day) for treatment of people with chronic pain due to malignancy.

The relief of acute pain may necessitate short term therapy with opioids. The availability of smaller pack sizes of S8 opioids would be suitable for these cases.

Pharmacists observe firsthand that prescribers tend to order a designated quantity such as the maximum quantity listed on the Pharmaceutical Benefits Scheme (PBS) or whatever pack size is readily available. Whilst best practice would dictate that the total quantity prescribed should reflect therapeutic need and dosing regimen, prescribers rarely order quantities less than the maximum Government-subsidised quantity or commercially available pack size quantity.

PSA believes that, too often, patients are dispensed a large pack size of opioid medicine on discharge from hospital and continue to receive prescriptions from their general practitioner based on the information in the discharge summary. A significant proportion of such patients are at risk of starting on their path towards addiction. The dispensing of opioids at the time of discharge from hospital could be limited to small pack sizes, or a referral made for a post-discharge Home Medicines Review for any high-risk patients.

When considering the small pack size option, many pharmacists voiced concerns about stock management and logistics. Firstly, when small pack sizes are introduced the range of products (and what stock a pharmacy needs to keep) will increase. In addition, often a sponsor will use the existing larger pack size container and simply reduce the content of the box or bottle. These factors are important considerations with S8 medicines which require storage in a safe. There can be significant impact on physical space requirements as well as cost. Some pharmacists have needed to invest in a larger custom-made safe or multiple safes to ensure compliance with state or territory storage requirements for the increasing range of S8 medicine stock on hand.

Concern has also been expressed regarding the trend observed by pharmacists that the introduction of smaller pack sizes invariably results in an increase in unit price of the medicine.

Option 2: Consider a review of the indications for strong opioids

The TGA will review indications for the S8 opioids and align them to current clinical guidelines for appropriate prescription of these products.

It is fundamentally important that the use of S8 opioids in Australia is aligned with contemporary clinical guidelines based on current evidence around indications and dosages relevant to the Australian population. PSA strongly supports a review of indications for S8 opioids as well as future regular updates.

A review of indications will also have other ramifications. For example, if there is a change in indication to reflect current evidence and this alters the approved indication on the Australian Register of Therapeutic Goods, this would trigger a review of the indication listed for subsidisation under the PBS.

Option 3: Consider whether the highest dose products should remain on the market, or be restricted to specialist / authority prescribing

Review the place of the higher dose S8 opioid products in the management of chronic cancer and non-cancer pain and whether certain high dose products should continue to be registered. Consider if specific controls, such as approval to prescribe through states and territories or the Pharmaceutical Benefits Scheme (PBS) should be introduced.

Option 3 is also closely linked to Options 2 and 7.

A review of indications and dosages relevant to clinical practice in Australia is likely to reveal if high dose products have a place in therapy.

Consideration also needs to be given to whether or not it would constitute best practice for a patient to be referred to a specialist at specific dose escalation points. This may determine whether additional controls such as restricting to specialist or authority prescribing is likely to provide better outcomes for patients.

There is concern however that additional controls on prescribers can also impact on access to medicines for patients. For example, pharmacists have cited possible inequities for patients in regional, rural or remote locations. To overcome such concerns, it may be necessary to consider alternative models that may better meet the needs of those patients.

One possible model is to allow any prescriber with appropriate skills to be able to apply for authorisation to prescribe high dose opioids but to have more stringent criteria for prescribers who do not have qualifications or specialist endorsement relating to pain management. The granting of an authority could also be linked to conditions (e.g. length of authorisation period, type of formulation of the medicine or strength of the medicine that may be approved, maximum quantity of medicine that may be prescribed, authorisation of any repeat prescriptions) depending on the prescriber's qualifications.

Even without instituting specialist or authority prescribing arrangements, PSA recommends consideration of other ways to minimise harm of opioid use and enhance quality outcomes, for example:

- supporting prescribers to implement an 'opioid trial' to determine the patient's responsiveness to opioid treatment[3]
- supporting prescribers to communicate to patients that up to three days' therapy of opioid analgesia is often sufficient for acute pain, and more than seven days' therapy is rarely needed[4]
- having agreed goals of therapy and timeframes which are accessible to the prescriber, patient and pharmacist; this may include discontinuing opioid therapy if goals are not achieved in the agreed timeframe
- providing appropriate tools for prescribers and pharmacists to best support patients and carers when discontinuing opioids in the community setting
- having shorter validity periods for hospital discharge prescriptions and facilitating appropriate transition of care
- continuation of opioids for pain management should be subject to clinical review by an independent prescriber or accredited pharmacist to ensure patient safety and quality use.

Relevant to this option as well as others in this consultation is for health professionals and policy makers to consider and agree on what is defined as benefits of opioid therapy, particularly in chronic therapy. For example, patient pain scores before, during and after an opioid trial could be used to guide short term therapy. However, for chronic non-cancer pain therapy, other measures such as improvement in functional status should be considered to guide whether therapy for an individual should continue or be ceased. The importance of considering functional measures together with, or even ahead of, level of pain relief is outlined[5,6,7] and this approach is already used in some places.[8]

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[3] The Royal Australian College of General Practitioners. Prescribing drugs of dependence in general practice, Part C: Key recommendations and practice points for management of pain with opioid therapy. East Me bourne: RACGP; 2017. At: **https://www.racgp.org.au/download/Documents/Guidelines/Opioid/Key-recommendations-and-practice-points.pdf**

[4] *ibid*.

[5] Chou R, Fanciullo GJ, Fine PG, et al. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. J Pain 2009;10(2):113-30.e22. At: **www.jpain.org/article/S1526-5900(08)00831-6/pdf**

[6] Berland D, Rodgers P. Rational use of opioids for management of chronic nonterminal pain. Am Fam Physician 2012;86(3):252-8. At: **https://www.aafp.org/afp/2012/0801/p252.pdf**

[7] The Royal Australian College of General Practitioners. Prescribing drugs of dependence in general practice, Part C2: The role of opioids in pain management. East Melbourne: RACGP; 2017. At: **https://www.racgp.org.au/download/Documents/Guidelines/Opioid/Addictive-drugs-guide-C2.PDF**

[8] Drugs of Dependence Unit, Queensland Government. Quick clinical guide for the use of opioids in chronic non-malignant pain. 2010. At: **https://www.health.qld.gov.au/__data/assets/pdf_file/0032/374693/ddu_quick_guide.pdf**

Option 4: Strengthening Risk Management Plans for opioid products

Review current risk management plans for opioids to determine whether they currently reflect best practice in opioid prescribing and management of risks.

PSA believes current risk management plans (RMPs) for opioids should reflect best practice in prescribing and management of risks and would support a review, given, as stated in the consultation paper, the registration of most opioid medicines occurred before RMP requirements were introduced in Australia.

The consultation paper refers to the focus of the United States Risk Evaluation and Mitigation Strategy on health care professional education and training. PSA would not support any proposal to include a mandatory requirement in RMPs in Australia for the sponsor to provide continuing professional development activities directly to health professionals.

Option 5: Review of label warnings and revision to the Consumer Medicines Information

Warnings could be placed on the packaging of opioid products identifying the risk of dependence and overdose and lack of efficacy in the long term treatment of chronic non-cancer pain, noting that the complexity of appropriate management of CNCP needs to be recognised. The CMI would also be reviewed to provide greater emphasis on risks of dependence, especially those associated with high doses.

PSA believes that a review of label warnings and CMIs is warranted particularly in the context of Option 2 (review of indications) and other options presented in the consultation paper, as well as TGA's work on reformatting Product Information.

In addition to the greater emphasis on risks of dependence (as suggested in the consultation paper), a CMI review would warrant consideration of information and advice on potential toxicities in people who are taking other medicines such as benzodiazepines.

Option 6: Consider incentives for expedited TGA review of improved products for pain relief and opioid antidotes

Provide priority review to new chemical entities that are viable alternatives to opioids for pain relief and also expedite the review of smaller pack sizes and/or abuse-deterrent formulations and products that can be used to negate the effect of opioids.

PSA is not certain that the provision of incentives will help solve the problems associated with opioids. Given the TGA has recently implemented a Priority review pathway for vital and life-saving prescription medicines, PSA would seek advice on whether this mechanism could be adapted for other medicines not meeting the current eligibility criteria under certain circumstances such as when there is a strong public health imperative.

The potential benefits of abuse-deterrent formulations are still uncertain. In Australia, an abuse-deterrent sustained-release formulation of oxycodone was introduced in 2014.

According to a 2015 study,[9] this resulted in short-term benefits of a reduction in misuse by injection and no clear switch to other drugs. A subsequent report[10] indicated that the use of higher strengths of controlled release oxycodone and misuse through tampering reduced while the use of other formulations increased, but that no significant effect was observed in terms of population-level opioid use or harm.

Option 7: Potential changes to use of appendices in the Poisons Standard to provide additional regulatory controls for strong opioids

Powers under medicines scheduling could potentially include controls of prescribing for particular populations or classes of medical practitioners, additional safety directions or label warning statements, specific dispensing labels.

This option is consistent with the mechanism which is already in place in the appendices of the current Poisons Standard. PSA is generally supportive of this type of arrangement to continue.

We are aware, however, that any changes would need to be adopted by states and territories to have effect. If changes are not uniformly adopted by jurisdictions, the outcome will not be ideal from a health practitioner and patient perspective as it may impact on equity of access and also create confusion.

Option 8: Increase health care professional awareness of alternatives to opioids (both Schedule 4 and Schedule 8) in the management of chronic pain

Existing clinical guidelines for the management of acute and chronic pain provide advice on the use of non-pharmacological and alternate pharmacological therapies for the management of pain. While these are available there may be limited health practitioner awareness and uptake.

Healthcare professionals have an obligation to maintain contemporary knowledge and possess appropriate skills within their scope of practice. As healthcare technology and therapeutic options evolve, it is necessary for pharmacists and prescribers to undertake relevant continuing professional development.

Education programs and awareness-raising initiatives are useful activities but need to be regarded as measures to support and complement other regulatory and non-regulatory options. We also suggest that an education program needs to be comprehensive. For example, it may be helpful to raise awareness about alternatives to S4 and S8 opioids in the management of chronic pain, but that must be presented in the context of opioids and their place in therapy more broadly. The inclusion of key messages that all health professionals

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[9] Degenhardt L, Bruno R, Ali R, et al. The introduction of a potentially abuse deterrent oxycodone formulation: early findings from the Australian National Opioid Medications Abuse Deterrence (NOMAD) study. Drug Alcohol Depend 2015;151:56-67. DOI: **https://doi.org/10.1016/j.drugalcdep.2015.02.038**

[10] Larance B, Dobbins T, Peacock A, et al. The effect of a potentially tamper-resistant oxycodone formulation on opioid use and harm: main findings of the National Opioid Medications Abuse Deterrence (NOMAD) study. Lancet Psych 2018;5(2):155-66. DOI: **https://doi.org/10.1016/S2215-0366(18)30003-8**

involved in the care of patients with chronic pain can deliver consistently to patients and carers (e.g. understanding that, with persistent pain, the primary aim might be to increase mobility and function rather than aiming to achieve absence of pain) will be important.

The provision of education and awareness-raising activities could also be informed by available data on opioid prescribing and dispensing. For example, 2013-14 opioid medicine dispensing data[11] showed significant variation between different local areas across Australian states and territories. The delivery of information and activities to support health professionals and patients could potentially be tailored for or target the high dispensing areas while also investigating local needs (for example, better access to pain specialists may be needed).

The review of clinical guidelines should be undertaken regularly, or when considered necessary by subject matter experts. In addition, professional bodies such as PSA should be appropriately resourced to develop practice support tools relevant to their profession or sector.

As suggested in the consultation paper the TGA-led Nationally Coordinated Codeine Implementation Working Group, established to support the implementation of the codeine rescheduling decision, is a model that could be considered if changes need to be implemented for S8 opioids. PSA believes that the Working Group generally operated well to facilitate a coordinated and consistent approach for all of the affected stakeholders in the dissemination of key messages and delivery of education and support materials.

Interprofessional events such as multidisciplinary conferences or Primary Health Network activities may be opportunities to present materials to different healthcare professionals and to consider the impact on professional practice.

PSA is also keen to work in collaboration with prescribers to assist with development and delivery of education at the grass roots level. An example would be an education program that pharmacists as medicines experts could deliver within general practices to prescribers and practice staff including other members of the multidisciplinary pain management team on ways to reduce harm associated with the use of opioids.

Comments on other specific issues

National real-time prescription monitoring system

The consultation paper mentions the implementation of a national real-time prescription monitoring system although this is not canvassed as a discrete option. PSA has long supported and advocated for a nationally uniform real-time recording and reporting system and re-iterates that such a system is a priority from a patient safety and public health perspective.

While the Australian Government's commitment to the implementation of the Electronic Recording and Reporting of Controlled Drugs (ERRCD) system is welcome, PSA is concerned that the response of states and territories has been variable. For a monitoring system to be

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[11] Australian Commission on Safety and Quality in Health Care. Australian atlas of healthcare variation. 2015. At: **https://www.safetyandquality.gov.au/wp-content/uploads/2015/11/Low-res-version-of-the-atlas.pdf**

informative for prescribers and pharmacists and able to effectively deliver maximal benefits to patients and families, it must be nationally uniform in terms of functionality and capability, coordinated between or across jurisdictions, and have the same medicines captured and reported. There must be interoperability of jurisdictional systems and databases, and seamless access by authorised health practitioners.

As stated in the consultation paper, states and territories "are responsible for the reporting and monitoring of prescription medicines within their jurisdiction". For some time, PSA has advocated for the adoption of nationally uniform regulatory controls for drugs and poisons. We still believe this is a fundamental parameter in order to achieve the best possible outcome from the use of a real-time monitoring system. At the very least, TGA can have an important role in encouraging states and territories to agree to which substances should be monitored.

The ERRCD system is intended to capture S8 medicines, however, PSA has consistently called for a monitoring solution which is compulsory and used for all medicines with the potential for addiction. Many S4 medicines as well as over-the-counter medicines are also subject to misuse. Pharmacists are also acutely aware that regulatory action such as rescheduling, particularly up-scheduling a substance, almost always results in misuse trends shifting to other medicines which may be in the same schedule or another schedule.

The Tasmanian Drugs and Poisons Information System Online Remote Access, referred to as DORA, has been regarded by health professionals as a valuable clinical tool. The recent inclusion of codeine, tramadol and dextropropoxyphene as relevant substances for real-time reporting in Tasmania was in response to evidence that these non-S8 substances are subject to misuse and that deaths have occurred as a result of unsanctioned use.[12] There have also been reports of other jurisdictions having plans to consider enabling legislative options to declare some S4 medicines as 'reportable'.

PSA has previously suggested that successful implementation of the ERRCD system is also dependent on appropriate workforce training.

Although the focus of this consultation relates to the misuse and overuse of S8 opioids, the significant public health problem involves all drugs of dependence. To design an appropriate response, PSA believes consideration of the broader problem is warranted rather than viewing S8 opioids in isolation. Identifying a possible solution for S8 opioids may be necessary for some aspects of the problem but this must be in the context of the impact that drugs of dependence more generally are having on patients and the community.

Also worth noting here is PSA's understanding that the Tasmanian DORA lists indications for medicines in the system. Such a feature will have relevance to the review of indications canvassed at Option 2.

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[12] Tasmanian Government Department of Health and Human Services. Codeine (3-methyl morphine) rescheduling. PSB Newsletter 53. 24 Jan 2018. At: **www.dhhs.tas.gov.au/__data/assets/pdf_file/0008/268667/Newsletter_53_Codeine_Scheduling_Changes_Jan_2018.pdf**

Owing prescriptions

Pharmacists have expressed significant concerns regarding the use of 'owing' prescriptions in practice. While owing prescriptions are not limited to the prescribing of opioids, it is a pertinent factor as pharmacists believe it contributes substantially to opioid misuse and perpetuates the problem. Pharmacists report that the use of owing prescriptions are particularly high in residential care facilities.

Medication charts

The National Inpatient Medication Chart was first introduced as a uniform medication chart in public hospitals with the aim of reducing prescription error and to standardise prescribing and administration documentation. Progress was made to minimise duplication and increase efficiencies by formalising the supply of medicines from a medication chart instead of requiring a prescription. A PBS-compliant Hospital Medication Chart can be used to prescribe, dispense, supply and claim PBS and RPBS items in public and private hospitals.

Despite these benefits, pharmacists believe that the use of charts promotes regular prescribing of PBS maximum quantities of strong opioids and regular administration in residential care facilities.

Pharmacists believe that any patient or resident on strong opioids should have the opportunity to receive a Home Medicines Review or Residential Medication Management Review more frequently than annually or every two years.

(End of submission)

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