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Technical and Safety Improvement Section
Pharmacovigilance and Special Access Branch
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Via online submission

**MIGA submission - TGA consultation -
Prescription strong (Schedule 8) opioid use and misuse in Australia**

MIGA appreciates the opportunity to make a submission on issues relating to the use and misuse of strong (Schedule 8) opioids in Australia, particularly options for a regulatory response.

A copy of MIGA's Submission is enclosed.

MIGA is a medical defence organisation and medical indemnity insurer advising, assisting and educating medical practitioners, medical students, healthcare organisations and privately practising midwives throughout Australia. Further details about its interest and involvement in prescription medication issues and the provision of healthcare more generally are set out in its Submission.

Please contact Timothy Bowen by telephone [REDACTED] or email [REDACTED] if you have any questions about MIGA's Submission.

Yours sincerely

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MIGA Submission

TGA consultation

Prescription strong (Schedule 8) opioid use and misuse in Australia

March 2018

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MIGA Submission - TGA consultation

Prescription strong (Schedule 8) opioid use and misuse in Australia

Executive summary

1. In answer to the options outlined in the TGA's consultation paper, *Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response (the consultation paper)*, MIGA supports:
 - Consideration of making different medication pack sizes available (Option 1)
 - Reviewing indications for Schedule 8 opioids to align them with current clinical guidelines (Option 2)
 - Reviewing current opioid risk management plans to determine whether they reflect best practice (Option 4)
 - A review of label warnings and revision to the Consumer Medicines Information (Option 5)
 - Increasing health professional awareness of alternatives to opioids in the management of chronic pain (Option 8)

It also has a number of additional comments and suggestions around these options.

2. MIGA has considerable reservations around the extent of proposals to restrict access to the highest dose products (Option 3) and changes to the Poison Standard appendices to restrict prescribing (Option 7). In particular, it does not support restricting access to certain practitioners or populations. Instead, it supports:
 - Reviewing indications for continuing use of highest dose opioid products
 - Ensuring the medical profession has the tools it needs, particularly through access to patient information, specialist services and education, to make appropriate prescribing and other treatment decisions for acute and chronic pain.
3. In addition, MIGA also supports:
 - Work towards a national, real-time prescription monitoring system
 - Examining how to enhance the capabilities of the Medicare Prescription Shopping Program
 - Further education of the medical profession around regulatory requirements
 - Consideration of initiatives to improve the access to pain management services, both on an outpatient and doctor-to-doctor liaison basis
 - Wherever possible and practical, harmonisation of regulatory regimes around the prescribing of Schedule 8 medications throughout Australia.

MIGA's interest

4. MIGA is a medical defence organisation and medical indemnity insurer with a national footprint which has represented the medical profession for over 115 years and the broader healthcare profession for over 17 years. Its members and policy holders including significant numbers of medical practitioners, medical students, healthcare organisations and privately practising midwives working throughout Australia in a variety of settings, including general and specialist practice, both in the community and in public and private hospitals.
5. MIGA's lawyers provide advice and assistance to its members on medico-legal issues arising out of prescription medication, which can include:
 - Understanding Schedule 8 medication prescription requirements
 - Managing aggressive or complex patients
 - Suspected "doctor shopping" or medication-seeking behaviour
 - Stolen prescription pads
 - Difficulties in accessing specialist services, particularly in pain management

This can involve advice to practitioners as well as assisting them with complaints and claims made against them.

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6. Recently MIGA has been involved in various consultations on prescription medication and medicinal cannabis in South Australia, Victoria and Queensland. It is also convening a series of boardroom dinners over the next couple of months, attended by key professional stakeholders, where one of the topics is *“The opioid epidemic – the human and claims costs - what can we learn from overseas experience and how is Australia managing this?”*
7. Through its Risk Management Program, MIGA provides a variety of education and resources, including materials specifically directed to medication issues and dealing with challenging and complex patient presentations. Over the last year, it has been running an interactive hypothetical session entitled *“Who dunnit? – A Poison Pill”*, which is a mock coronial inquest exploring the prescribing challenges faced by medical practitioners and the risk of harm from prescription drug toxicity. It covers issues such as the potential for medication misuse, addictive medications and complex patient presentations.

Option 1 - Consider the pack sizes for Schedule 8 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

8. MIGA supports Option 1, which would make a range of more suitable and smaller pack sizes available for patients using opioid medication.
9. This reform could go some way to addressing issues which MIGA has seen in medico-legal matters around patients having access to a greater supply of opioids than is helpful to them, often because there are limited pack size options or difficulties in sourcing other medication dispensing limitations.
10. It is important that larger pack sizes remain available for appropriate indications at discretion of prescribing doctor.
11. Introduction of this reform would require education of medical practitioners on the availability of various dispensing options, and of the community on why this is an appropriate step.
12. In addition, work needs to be undertaken with electronic health record programs and other eHealth platforms to ensure that there are no ‘default’ prescription options (i.e. a certain number of tablets) for opioids.
13. As suggested in the consultation paper, MIGA supports examining Pharmaceutical Benefits Scheme (PBS) listings to ensure they match developing clinical standards, with input from peak professional group.
14. Another necessary step is to address patient attitudes and behaviours which driver longer-term prescriptions, such as addiction and convenience. Clearly this is a broader issue, with input from a variety of professional and community perspectives required.

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.

15. MIGA supports this proposal on the basis that it is undertaken with input from peak professional groups and various governmental health departments, a number of whom have already provide significant and useful clinical guidance on opioid use.
16. It is import to focus on consistency and clarity between product registration, descriptions and information on the one hand, and clinical indications and guidelines on the other.

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17. MIGA supports better and clearer guidance and education for the medical profession on indicia for pain medication use for chronic non-cancer pain. It recognises a number of groups, including the NPS MedicineWise, the Royal Australian College of General Practitioners and the Australian and New Zealand College of Anaesthetists Faculty of Pain Medicine, have made concerted efforts to develop guidance and education for the medical profession on acute and chronic pain management, particularly the use of opioids. The challenge is now to ensure that this material is known and available throughout the profession, and continues to develop to address the wide range of scenarios which practitioners face in managing acute and chronic pain patients.

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. We would consider if specific controls, such as approval to prescribe through states and territories or the PBS should be introduced.

18. MIGA supports a review, in consultation with key professional groups, around indications and use of highest dose opioid products. However, it does not support restrictions on which medical practitioners can prescribe various opioid medications.
19. The issues around whether certain opioids should remain on the market, or have additional restrictions placed on their prescription, are complex and require both careful consideration and broad consultation.
20. MIGA defers to peak professional groups on the role of higher dose schedule 8 medications for chronic cancer and non-cancer pain, and whether certain products should continue to be registered. However MIGA's position is that if there is a clinical indication for a medication, it should be available to prescribe.
21. Proposals for specialist only prescribing raise important issues around access to appropriate services, particularly pain specialists and multi-disciplinary pain clinics. They do not acknowledge that many general practitioners have the necessary skills and experience to prescribe these opioids for appropriate clinical indications.
22. The better approach is to ensure that all medical practitioners have the necessary information and guidance for prescribing opioids. In particular, this includes access to real-time prescribing systems, enhancement of the Medicare Prescription Shopping Program, access to appropriate specialist services for advice and referral, and easy availability of appropriate guidance and education.
23. In addition, where restrictions would have no impact on the issuing of private prescriptions, this suggests there is little merit in restricting certain PBS prescriptions to specialists.
24. There may be merit in considering use of authorities for certain higher dose opioids, particularly if this would be linked to the Medicare Prescription Shopping Program. However, in MIGA's experience the use of authority prescriptions of themselves are not generally a useful control mechanism to avoid opioid misuse.

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.

25. MIGA supports a review of current risk management plans to determine whether they remain clinically appropriate, with input from key professional groups, and a focus on providing education to the medical profession. It believes considering how well they focus on education for those prescribing medication could be very helpful.

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26. It believes education is best co-ordinated by a peak body such as NPS MedicinesWise, in conjunction with key professional groups and government health departments. It does not support suppliers having responsibility for education development and delivery. However, there is merit in the United States approach of requiring suppliers to fund appropriate education relating to their products.

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

Under this option, 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 chronic non-cancer pain needs to be recognised. The CMI would also be reviewed to provide greater emphasis on risks of dependence, especially those associated with high doses.

27. MIGA supports the proposal to provide clearer warning labels on opioid packaging relating to risks of dependence and overdose, and lack of efficacy for certain uses. However, it queries their potential effectiveness and appropriateness.

28. It is concerned that such information could be misunderstood by patients and / or taken out of context, calling into question a clinically appropriate prescription by an appropriately trained and educated medical practitioner.

29. MIGA supports clearer information being available to patients on the potential downsides of opioid use, but in the right context. That would normally be the provision by a medical practitioner to a patient of information developed by peak professional groups, where the relevance for the patient's particular presentation can be explained properly. In particular, it sees a role for more "*patient friendly*" information on risks, based on professional consensus guidance, similar to that produced by various professional colleges and associations for surgical treatments.

30. It questions the effectiveness of medication disposal programs, but agrees they are worth considering as part of a more holistic response to dealing with opioid use and misuse.

31. It agrees that the Consumer Medications Information should mirror the Product Information.

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.

32. MIGA has reservations about the potential for using the Poisons Standard to restrict opioid prescribing to particular populations or classes of medical practitioners. It sees this as too "*broad brush*" and not reflecting the complexity of the issues involved.

33. As set out above, the better approach is to focus on ensuring availability of appropriate guidance for all medical practitioners who may prescribe opioids or manage acute and chronic pain patients, access to education and specialist support, and increased availability of pain specialists and multi-disciplinary clinics for referral as necessary.

34. Restricting opioid prescribing to classes of patients cannot appropriately deal with the clinical complexities of what patients may require opioids, and in which patients there are not justified. These are matters for clinical judgment, informed by appropriate guidelines and education.

35. As set out above, restricting opioid prescription to particular classes of medical practitioners raises significant issues around access to appropriate services, particularly in outer suburban and regional areas,

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and for patients who need to rely on the public hospital system and / or Medicare to fund their care and treatment. It also unnecessarily and inappropriately denies medical practitioners who have sufficient skills and experience in this area to practice within their skill set and overcome at least some of these access issues.

36. The comparison to restricting access to medication for severe acne is not a clear one. Acute or chronic pain are much more common clinical scenarios for medical practitioners than patients seeking particular medication to treat severe acne.
37. In terms of the option of mandatory education raised in the consultation paper, MIGA believes it would be better to focus first on the initiatives around access to services and education already identified above and in the consultation paper. It accepts there may ultimately be merit in considering mandatory education requirements for those prescribing certain higher dose opioids. However, these would need to be reasonable and not unduly burdensome. Peak professional groups would need to be consulted about the practicality of such a proposal.

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.

38. MIGA strongly supports the option of increasing health professional awareness of alternatives to opioids in the management of chronic pain, building on existing initiatives by various government and professional organisations.
39. As suggested in the consultation paper and above, collaboration between the TGA, NPS MedicinesWise and clinical colleges would be the appropriate way forward. Subject to the views of those bodies, it may also be appropriate to include various government health departments, given the amount of guidance they provide in this area.
40. It is important that such guidelines, where possible and practical, reflect consensus opinions amongst the medical profession, deal with practical issues such as access to appropriate services, and are both widely publicised and are available in a variety of platforms. In particular, it would be helpful if such guidance could include decision-making tools and case studies, reflecting the broad and complex nature of pain presentations.

Additional issues

41. Although MIGA recognises that the TGA's role and powers around opioid use are limited, this consultation raises broader issues where the TGA and a range of other stakeholders have significant interests.
42. Given MIGA sees this consultation as part of a continuing governmental, professional and community dialogue around opioid use, it raises a number of other issues for consideration below, namely around real-time prescription monitoring, the Medicare Prescription Shopping Program, education on regulatory requirements, initiatives to improve access to appropriate services and harmonisation of various prescribing regimes.

(a) Real-time prescription monitoring

43. MIGA supports introduction of a real time prescribing system accessible by medical practitioners during consultations with their patients. It would like to see such a system introduced as soon as practical throughout Australia.

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44. Multiple coronial inquests throughout Australia have identified such a system would be a significant initiative in trying to reduce “*doctor shopping*” and over-prescribing of particular medications, potentially saving lives and improving health and well-being of patients more generally.
45. It is imperative that various systems throughout Australia can share information with each other. In MIGA’s experience, the misuse of prescription medication by one or more patients can cross different states and territories.
46. The system should include all prescription opioids and other medications with a high risk of potential misuse, including both Schedule 8 medications and other medications. MIGA defers to peak professional groups on particular medications which are not classed Schedule 8 medications that should be included in such a system. However, there is merit in all opioids being included.

(b) Medicare Prescription Shopping Program

47. The Medicare Prescription Shopping Program is a useful service for medical practitioners to assess whether a patient could be misusing prescription medication.
48. If a patient is on the program, a medical practitioner can be provided with:
 - The number of individual prescribers for PBS medicines supplied by pharmacies during a certain period
 - PBS medicines supplied to the patient, including the total number prescribed and the pack size.
49. This is a useful program for medication practitioners, but with its limits, including:
 - The program defines a “*prescription shopper*” as a person who, within a three month period, has received prescription medications from six or more different prescribers, or been supplied 25 or more target, or 50 or more of any, pharmaceutical benefits, which are relatively arbitrary and would not identify all patients who may be misusing prescription medication
 - The program does not identify medications prescribed outside the Pharmaceutical Benefits Scheme (PBS), i.e. on a ‘private’ basis
 - There can be delays associated with relevant information being ‘loaded’ onto the program.
50. MIGA supports a review of how the program could usefully and practically evolve to better identify the range of patients who may be potentially misusing prescription medication, taking into account developing understandings around clinical and community issues involving these medications.

(c) Education on regulatory requirements

51. MIGA is concerned that the relatively complex requirements of regulatory regimes for the prescription of these medications are not well understood amongst the medical profession.
52. For those practitioners who are not prescribing medications with a potential for misuse on a regular basis, knowing and understanding these regulatory regimes can be challenging. It can also lead to unintended breaches in good faith, and potential civil penalties and disciplinary action.
53. In addition to the clinical guidance already suggested above and in the consultation paper, there should be broader guidance dealing with the requirements of the various regulatory regimes.
54. Some material is already provided by various health departments, but these are not necessarily well-known amongst the profession.

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(d) Initiatives to improve access

55. MIGA has seen the challenges which its members and policy holders have faced in managing patients requiring or seeking opioids in a context where there is limited access to appropriate specialist services.
56. The inevitable realities of limited resources in providing appropriate specialist services are acknowledged.
57. MIGA believes there is scope for careful consideration of practical initiatives to improve access to pain management services and other relevant specialist services, both on an outpatient and doctor-to-doctor liaison basis, in areas where they are most needed.
58. The availability of appropriate specialists for other medical practitioners to consult when facing challenges in this area could be very helpful in reducing potential opioid misuse.

(e) Harmonisation of Schedule 8 prescribing regimes

59. MIGA supports, wherever possible and practical, harmonisation of regulatory regimes around the prescribing of Schedule 8 medications throughout Australia.
60. Medical practitioners can manage patients who are prescribed a Schedule 8 medication elsewhere in Australia, and varying requirements can lead to confusion and patient dissatisfaction.
61. MIGA sees considerable merit in taking steps towards harmonisation of Australian Schedule 8 medication regimes.