

15 January 2020

Senator Rachel Siewert
Chair
Senate Community Affairs References Committee

Via online submission

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Dear Senator

MIGA submission – Medicinal cannabis regulation and education

1. As a medical defence organisation and medical / professional indemnity insurer, MIGA appreciates the opportunity to contribute to the Committee's inquiry, *Current barriers to patient access to medicinal cannabis in Australia*.
2. Its Submission deals with issues around medicinal cannabis regulation, education and training, and access to appropriate healthcare, arising from the inquiry's terms of reference (a), (c), (e), (g) and (k). It addresses them from medico-legal, health regulatory and risk management perspectives.
3. MIGA takes no position on merits of and indications for medicinal cannabis use. These are matters for clinical professional interests.

MIGA's position

4. MIGA supports
 - Regulation of medicinal cannabis prescription and use which ensures an appropriate balance between protection of the public and obligations which are sensible, fair and practical
 - Prescription of medicinal cannabis being based on existing Therapeutic Goods Administration (TGA) and state and territory schedule medicines regimes
 - Greater moves towards national uniformity in these regulatory processes
 - Ensuring patients, doctors, other health professionals and the community have clear understandings of clinical indications for medicinal cannabis, and obligations around its prescription and use.
5. In considering issues of regulation, professional discipline and education around medicinal cannabis, recent experiences with opioid and off-label medication warrant examination. Such experiences may assist in addressing comparable challenges in prescription and use of medicinal cannabis.

MIGA's interest

6. MIGA is a medical defence organisation and medical / professional indemnity insurer advising, assisting and educating medical practitioners, medical students, healthcare organisations and privately practising midwives throughout Australia.
7. With over 34,000 members throughout Australia, MIGA has represented the medical profession for 120 years and the broader healthcare profession for 17 years.
8. MIGA has contributed to
 - Earlier Queensland consultations which led to development of a bespoke medicinal cannabis regulatory scheme
 - Later South Australian and Queensland consultations on integrating medicinal cannabis prescription and use within existing schedule medications regimes.

9. MIGA has a broad range of education initiatives for its members, clients and the wider healthcare professions. These include recent interactive hypothetical sessions on medication prescription challenges delivered across Australia, and interactive online education on each of opioid medication and medication prescribing more generally.
10. Its experience in advising, assisting, educating and advocating for medical practitioners, medical students, healthcare organisations and privately practising midwives working throughout Australia in a variety of settings gives it particular insights into issues around prescription and use of medicinal cannabis and medication more broadly. It allows comparison of the challenges faced in certain areas, such as opioid and off-label medication prescription and use, with how those challenges might affect other areas, such as medicinal cannabis prescription and use.

Terms of Reference

- (a) Appropriateness of the current regulatory regime through the TGA Special Access Scheme, Authorised Prescriber Scheme and clinical trials**
- (c) Interaction between state and territory authorities and the Commonwealth, including overlap and variation between state and territory schemes**

Merits of existing regulatory processes

11. MIGA supports use of existing TGA and schedule medicines processes to regulate the prescription and use of medicinal cannabis.
12. It has supported state and territory governments moving away from bespoke medicinal cannabis regulatory schemes towards regulatory schemes based on existing schedule medication regimes.
13. Although bespoke medicinal cannabis regulatory regimes in various states and territories were able to focus on issues unique to a new and emerging area of practice, they raised a range of other challenges. These included lack of regulatory consistency, potential for confusion, duplication of processes and issues of appropriate patient access, particularly in rural and remote areas.
14. MIGA would like to see further steps towards national consistency in regulatory processes around medicinal cannabis prescription and use.
15. As the TGA's role and approach is nationally consistent, there does not appear to be compelling reasons for variations in state and territory prescription regulatory processes. These differences can cause confusion and uncertainty for the medical profession, their patients and the community. They include
 - When a single application can be made for both TGA and state / territory health department approval to prescribe medicinal cannabis, and when separate applications to both the TGA and relevant health department are required
 - Different state or territory requirements for health department authorities around Schedule 8 medicinal cannabis medications
 - Classes of doctors allowed to prescribe medicinal cannabis.

Comparing experiences in opioids and off-label medications

16. Medicinal cannabis generally involves use of Schedule 8 medications, which are drugs of dependence, in an emerging and debated range of clinical scenarios.
17. From a regulatory perspective, the issues involved are comparable with those involved in
 - Opioid medication, which are also usually Schedule 8 medications, and
 - Off-label prescribing, where clinical indications can also be emerging and open to clinical professional debate.
18. Regulatory issues which apply to each of medicinal cannabis, opioids and off-label medication prescription and use include
 - Need for national harmonisation of Schedule 8 prescribing regimes wherever possible and practical, reducing the risk of misunderstanding and inconsistency

- Potential value of real-time prescription monitoring systems sharing information across states and territories
- Scope for greater use of the My Health Record system, particularly to ensure doctors have up-to-date access to key clinical information about their patients
- Relative lack of professional awareness and understanding of complex regulatory requirements, which can lead to unintended breaches in good faith, with potential for civil penalties and disciplinary action
- Recognition of various challenges involved in accessing specialist medical care outside the primary care setting.

Medicinal cannabis and professional discipline

19. In an evolving and debated field of practice, it is important that professional regulation and discipline strikes the right balance between public protection and fairness to the medical profession.
20. For doctors not prescribing medicinal cannabis on a regular basis, knowing and understanding the relevant regulatory regimes and guidance can be challenging. Given they are relatively complex, this can also be the case for doctors who are more familiar with relevant clinical and regulatory requirements. Inevitably there can be “grey areas” and debates around clinical indications, advice to patients and ongoing care.
21. Limitations in professional understanding and education can lead to unintended, good faith breaches of prescription medication regimes by doctors. Professional regulation and discipline can respond to this in different ways across Australia. Depending on which state or territory the breach occurs, there can be greater chances of pecuniary penalties or disciplinary sanction in one state or territory as compared to another. This is undesirable and unwarranted.
22. As is the case for opioid and off-label medication prescription and use, a nationally consistent approach towards professional regulation and discipline in medicinal cannabis prescription and use is required. This involves a graded approach of
 - Counselling and education first, whether by state and territory health department bodies and / or professional regulators (such as the Medical Board of Australia)
 - Consideration of professional discipline only in cases of serious, or persistent, regime breaches
 - Civil penalty prosecution only pursued where absolutely necessary, i.e. where the professional regulator cannot appropriately deal with the matter, and providing reasonable excuse defences to such prosecutions based on a reasonable belief in good faith of acting in an appropriate manner.

Terms of Reference

(e) Availability of training for doctors in the current TGA regulatory regime for prescribing medicinal cannabis to their patients

(g) Sources of information for doctors about uses of medicinal cannabis and how these might be improved and widened

23. Drawing from issues around opioid and off-label medication prescription, for medicinal cannabis concerted and targeted education and training efforts are needed across the country to ensure doctors are aware of
 - Regulatory requirements for prescription – some material is already provided by various health departments, but it is not necessarily well-known or quickly accessible
 - Accepted clinical indications and contraindications – again the TGA and other professional groups have produced important material, but more is needed
 - Authoritative information and services which can be consulted.
24. Wherever possible, education and other resources should be available in a variety of platforms, including Apps, and in a variety of formats, particularly those offering clinical decision-making tools and examples.

25. MIGA has seen significant numbers of medico-legal matters, including disciplinary cases and coronial inquests, arising in relation to the prescription medication where regulatory requirements have been misunderstood or not properly appreciated and / or where clinical indications for use have been debated and uncertain. This supports the need for better and targeted education and training.
26. MIGA acknowledges the significant efforts made by Australian Governments and clinical professional groups around providing guidance on clinical indications for medicinal cannabis.
27. The role of NPS MedicineWise in educating the health professions and community around the role and use of opioid medication and its “*Choosing Wisely*” campaigns have been very important and valuable. Whether it can play a similar role around medicinal cannabis is worthy of consideration.

Term of reference

(k) Particular barriers for those in rural and remote areas in accessing medicinal cannabis legally

28. MIGA has seen the challenges which its members and clients face in managing patients where there is limited access to appropriate specialist services, particularly around Schedule 8 medications where specialist input may be required.
29. Some patients may have difficulty in accessing treatment in a timely manner, particularly those in rural locations or who are on public hospital outpatient clinic waiting lists.
30. MIGA acknowledges the inevitable realities and limitations in providing appropriate specialist services across Australia. However it believes there is scope for practical initiatives to improve access to specialist services, both on an outpatient and doctor-to-doctor liaison basis.
31. The availability of appropriate specialists for doctors to consult when facing challenges around prescription and use of medicinal cannabis could be very helpful in ensuring its appropriate prescription and use.
32. If you have any questions or would like to discuss, please contact Timothy Bowen,

Yours faithfully



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