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11 July 2016

Ms Deborah Jeffrey
Research Director
Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee
BRISBANE QLD 4000

Via email: medicinalcannabis@parliament.qld.gov.au and post

Dear Ms Jeffrey

MIGA submissions on Public Health (Medicinal Cannabis) Bill 2016

MIGA welcomes the opportunity to provide a submission to Committee's inquiry into the Public Health (Medicinal Cannabis) Bill 2016 (Qld) (**the Bill**).

Our focus is on issues relating to operation of the Bill from a medico-legal perspective.

This submission follows a previous submission which MIGA provided to Queensland Health on an earlier version of the Bill (**MIGA's initial submission**).

MIGA's interest

MIGA is a medical defence organisation and medical indemnity insurer that has represented the medical profession in particular for in excess of 100 years. It has a national footprint and is one of a small number of medical indemnity providers in Australia. It offers a range of medical indemnity insurance products and associated services to the health care profession across Australia.

MIGA insures medical practitioners, health care companies, privately practising midwives and medical students, both in Queensland and throughout the rest of Australia. Its members and policy holders include a broad range of specialties across the medical profession.

On a daily basis, MIGA's lawyers advise its members and policy holders on a variety of medico-legal issues, including those arising out of medication prescription. These issues include:

- ensuring regulatory requirements for medication prescription are met, such as various state and territory requirements for Schedule 8 medication prescription and use of the Commonwealth *Therapeutic Goods Act* Special Access Scheme

- 'informed consent' requirements prior to medication prescription

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- managing patients who present particular challenges for medication prescription, such as those facing addiction issues

- disciplinary, coronial and civil damages matters arising out of medication prescription

MIGA's position

MIGA makes this submission in its role as representing the interests of its members and policy holders.

In doing so, MIGA takes no position on either the clinical or ethical grounds for the Bill and the proposed regime for regulating the prescription and dispensing of medicinal cannabis in Queensland.

MIGA supports wide engagement with appropriate stakeholders, particularly peak professional and patient bodies in relation to the need for, and appropriateness of, use of medicinal cannabis in Queensland.

MIGA's submissions are directed to medico-legal and other practical issues arising out of the operation of the proposed regime, if passed by the Queensland Parliament into law.

Firstly, MIGA addresses some general issues relating to the proposed regime, before dealing with a number of individual provisions in the Bill.

1. General issues

1.1 Education

It is clear that the nature of the proposed regime means that much will need to be done to educate patients, the health profession and the public on what it involves and what it will require.

The inherent controversies relating to the use of medicinal cannabis, coupled with the widespread illicit use of cannabis, mean that health professionals will need to be very clear about what their obligations are under a new regime, and to have a thorough understanding of best ways to practice using the regime.

MIGA supports the public awareness measures already outlined in the Minister for Health's speech introducing the Bill into Parliament.

In particular, MIGA sees a need for such a campaign to involve a comprehensive education program for patients, the health profession and the public about the proposed regime. This would need to be developed well before the proposed regime is implemented so there is sufficient time available for proper education to occur before the regime commences.

MIGA considers it imperative that the education occur before the regime begins, so health professionals are not learning obligations under a new, unique regime as they see patients warranting medicinal cannabis prescription.

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1.2 Ongoing review

In MIGA's initial submissions, it had suggested the proposed regime be subject to review within two years of implementation, particularly to identify any lessons which can be learned from its implementation and whether there is a need for changes to the regime, or additional reform, as part of working towards a comprehensive national approach to the use of medicinal cannabis.

MIGA is pleased to see the Bill is consistent with the position it advocated for review of the new regime within two years of implementation.

1.3 Patient-class prescribers

MIGA supports the category of patient-class prescribers provided for in the Bill.

It notes this category was not part of the earlier version of the Bill, where scope to prescribe medicinal cannabis was restricted to approved prescribers only, with approvals being provided following an administrative process.

As outlined in MIGA's initial submissions, it had been concerned that despite the merits of such a relatively 'centralised' case-by-case decision making model, it may pose some practical issues, particularly given the broad nature of the issues to be considered and the evolving and relatively controversial nature of the use of medicinal cannabis generally. Its concerns were similar to those raised by the Victorian Law Reform Commission on a similar model, including issues of administrative costs, uncertainty, appeals and treatment delays.

MIGA believes the addition of the patient-class prescriber category addresses many of those concerns.

1.4 Indemnity issues

In the transcript of the Queensland Health briefing to the Committee on 15 June 2016, questions were raised about potential insurance / indemnity issues for health professionals who participate in the proposed regime.

To the extent it would assist the Inquiry, MIGA may be in a position to provide further information in response to specific concerns or other issues in the minds of Committee members.

2. Individual Bill provisions

2.1 Chapter 3 generally – patients eligible for medicinal cannabis approval

Chapter 3 of the Bill does not exclude 'eligible patients' under Section 54 of the Bill from being the subject of an application under Chapter 3 of the Bill.

However, the Minister of Health's explanatory speech introducing the Bill referred to Chapter 3 approvals being used where a patient was 'ineligible' to be treated by a patient-class prescriber.

Obviously, where a patient could be an 'eligible patient' under the Bill they should pursue that option. However, there may be circumstances, such as remote location or other access difficulties, which may preclude timely access to a patient-class prescriber.

It may be that the Chief Executive of Queensland Health (**the CEO**) would not reject applications under Chapter 3 on the grounds that they should instead be made on the basis under Chapter 4, Part 2 as an eligible patient. However, MIGA raises this potential issue of uncertainty for consideration and clarification, perhaps through subsequent guidelines and education of the profession and patients.

2.2 Section 10 – Suitability of person to hold approval

In terms of the criteria which the CEO can investigate in determining whether someone should be an approved prescriber of medicinal cannabis, MIGA agrees a prescriber must be a fit and proper person, possessing appropriate qualifications and experience, to prescribe medicinal cannabis.

MIGA's concerns about the proposed provision relate to:

- the extent of investigations which would be required to ascertain suitability to be a prescriber, particularly for those who have previously sought, and been granted, such status

- uncertainty about the nature of the evidence which an applicant may need to provide to the CEO

MIGA suggests consideration be given to developing guidelines on what is expected of an applicant for approved prescriber status, particularly their qualifications and experience, character and standing, and knowledge and understanding of the requirements of the proposed regime.

Absent guidance, MIGA foresees a considerable administrative burden on all involved, possible inconsistent assessment processes where delegates are involved in the process, and potentially unnecessary delays in treatment.

It also suggests that consideration be given to a process by which applicants who have previously been granted approved prescriber status could face a streamlined approval process in terms of assessing their suitability. In particular, information from any previous application/s could be retained and further investigations restricted to matters post-dating the last application.

2.3 Section 11 – Suitability of patients to undergo treatment with medicinal cannabis

When determining whether a patient is suitable to use medicinal cannabis for clinical purposes, it is clear that they must be suitable both from personal and clinical perspectives.

MIGA has reservations about the decision-making process contemplated, particularly:

- the extent to which a 'two-tier' system of regulation is created, whereby patients who see a patient-class prescriber to consider possible medicinal cannabis treatment do not face the same assessment of personal circumstances and criminal history as would those seeing a single patient prescriber

- uncertainty as to the nature of "*personal circumstances*" which would be relevant

- what would constitute "*relevance*" of a patient's previous criminal history and the extent to which this could mean certain patients are permitted to use medicinal cannabis, and others are not

- the CEO's discretion, but not obligation, to seek advice of the expert advisory panel, making it unclear on when and how the CEO would take advice on these issues

- uncertainty about when specialist medical practitioner's opinion would be considered necessary and relevant

MIGA does not see a need for wholesale changes to the proposed decision-making model for single patient prescribers. Instead, it proposes the following:

- consideration be given to a regime, whether through regulation or guideline, where 'eligible patients' under Section 54 of the Bill who may have difficulties in seeing a patient-class prescriber because of location and / or accessibility issues, could still access medicinal cannabis on the same terms as another eligible patient able to see a patient-class prescriber. This could involve joint management by a patient-class prescriber and an approved prescriber and / or a streamlined or expedited scheme of assessment of suitability for treatment

- provision of detailed guidelines identifying the "*personal circumstances"* of a patient which may be taken into consideration, which are publicly available

- if an application is proposed to be rejected on the basis of the patient's "*personal circumstances*" and / or criminal history, it be mandatory for the CEO to seek the advice of the expert advisory panel before making a final decision

- consideration be given to whether timeframes for approving applications for patients who have demonstrated urgent need, such as terminal illness or other compelling reason, can be expedited

2.4 Sections 15 and 16 – Written consent and specialist opinion requirements

MIGA sees inherent uncertainty with general requirements to:

- obtain written consents to medicinal cannabis treatment

- the matters which should be addressed in a written opinion from a specialist medical practitioner

Given those uncertainties, it proposes that guidelines be developed to set out matters to be addressed in both:

- written consents, particularly the extent of information which should be provided to a patient

- written opinion from a specialist medical practitioner, particularly as to various factors which would need to be considered to make the opinion of any utility to the CEO and expert advisory panel

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2.5 Section 24 – Criteria for grant of medicinal cannabis approval

MIGA is concerned that there may be situations where a patient is considered suitable for medicinal cannabis treatment on both personal and clinical grounds, but the application is refused on the basis that the applicant to be the approved prescriber is, for whatever reason, rejected.

To ensure that appropriate patients are still afforded timely access to treatment, MIGA suggests that consideration be given to an appropriate mechanism by which such patients can still obtain treatment in a timely manner through a suitable approved provider.

This mechanism could be achieved by a process whereby a register is kept of approved providers, and an expedited process can be used for finding another approved provider for the patient in question.

2.6 Section 27 – CEO may require information or documents

MIGA accepts that it may be necessary to make further inquiries about both the applicant and patient before making a decision on the application to provide medicinal cannabis.

Its concern is that with respect to the applicant there is no limitation on the nature of the information which can be sought.

Although MIGA would like to think that such investigation would be directed to only matters relevant to determining the applicant's suitability to be an approved provider, this is not explicitly stated.

MIGA suggests that consideration be given to specifying in Section 27 of the Bill that only matters relating to the applicant's suitability to hold the approval may be subject to an information requirement notice.

2.7 Sections 28 and 30 – Criminal history report

MIGA accepts that as part of determining an applicant's suitability to be an approved prescriber it may be necessary to investigate whether they have any criminal history.

Consistent with the position taken in Section 10 of the Bill about criminal history only being considered where relevant to the application, MIGA believes that Section 28 of the Bill should limit the CEO to asking for a written report about the criminal history only to the extent that it is relevant to determining the applicant's suitability to be an approved prescriber.

In addition, MIGA also proposes the following consequential amendments:

- Section 28 - the information provided by the Commissioner of Police be limited to only that which is relevant, avoiding unnecessary disclosure and breaches of reasonable privacy in terms of unrelated issues, such as driving offences, and reducing administrative burden on the CEO

- Section 30 - the Commissioner of Police is only required to notify the CEO about a change in an applicant's criminal history to the extent that it is relevant to their suitability to be an approved prescriber

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2.8 Sections 32 and 33 – Timeframe for decision

MIGA recognises that decisions on whether to grant an application for use of medicinal cannabis may be complex.

However, it is concerned by a process which contemplates up to three months, or even longer, being required to determine applications, and applications automatically lapsing after three months if no formal extension is granted.

In particular, there appears to be no mechanism for expedition of this process in more straightforward, or urgent, cases.

MIGA proposes consideration be given to a mechanism by which applications involving no questions as to an applicant's suitability to prescribe, or a patient's suitability to be treated with medicinal cannabis, can proceed more quickly.

It would seem necessary and appropriate that there be a process for 'triaging' applications, so as those which are more urgent or 'straightforward' are not subject to any unnecessary administrative delay.

2.9 Section 52 – Prescription of medicinal cannabis other than under medicinal cannabis approval

As set out above, MIGA supports the addition of the patient-class prescriber category to the Bill.

It sees a need for wide consultation with peak professional bodies on classes of specialist medical practitioners to be included as patient-class prescribers, types of medicinal cannabis which may be used, and patients to be included as eligible for this aspect of the new regime, both initially and into the future.

MIGA supports the inclusion of specialists already contemplated, namely paediatric neurologists, oncologists and palliative care specialists, as patient-class prescribers.

In terms of requirements to be set out in regulations relating to:

- the way in which specialists may exercise their authority under the proposed regime
- codes, guidelines, protocols of standards to be complied with
- events giving rise to a requirement for a specialist to notify the CEO

MIGA proposes wide consultation on the content of such requirements, including with peak professional and patient bodies. In particular, MIGA would appreciate the opportunity to contribute to that process.

2.10 Sections 75 and 95 – Potential offences by prescribers

Sections 75 and 95 of the Bill provide for offences by persons, including prescribers, for non-compliance with approval conditions or medicinal cannabis management plans.

In addition, the proposed regime contemplates that single-patient and patient-prescribers will commit an offence under the *Drugs Misuse Act 1986* (Qld) if there is a contravention of the conditions of approval, or proposed regime generally (as set out in the Queensland Health briefing to the Committee on 15 June 2016, page 2).

The concerns which MIGA hold about such provisions are to a large extent consistent with those set out on pages 6 and 7 of the Explanatory Notes to the Bill. These suggest the most likely contraventions would be a failure to comply with narrow limits of approval, which would constitute a crime under the *Drugs Misuse Act*.

The notes acknowledge that such activities may not be 'criminal', perhaps arising from treatment decisions made in good faith.

MIGA agrees with the position set out in the notes that the Bill should contain offences to deter non-compliance and enable appropriate enforcement action when warranted.

However, it is troubled that all breaches by prescribers would fall for consideration of criminal action, with any decision based on discretionary criteria yet to be determined.

Although MIGA supports the contemplated liaison between Queensland Health and the Queensland Police Service about formal process for enforcement action, it believes more is required.

MIGA proposes that Queensland Health, regulators such as AHPRA, Medical Board of Australia (including its Queensland Board), the Office of the Health Ombudsman and police work together to produce a set of guidelines, with input from peak professional bodies and medical defence organisations such as MIGA, which identify what breaches would be dealt with by each of professional regulators, Queensland Health and the police.

2.11 Section 81 – Decision to take administrative action

MIGA endorses the need for a process whereby approval can be suspended or cancelled because of issues relating to the approved prescriber.

However, it is concerned that patients, who may have nothing to do with issues relating to the approved prescriber and where there are no issues relating to their suitability for medicinal cannabis, are adversely affected by such actions.

Consistent with the position set out above, MIGA suggests that consideration be given to a mechanism by which treatment with medicinal cannabis for such patients could be transferred to another approved provider, perhaps one retained on a register kept by the CEO.

2.12 Section 85 – Chief Executive may inform Boards about particular matters

Consistent with procedural fairness, MIGA respectfully suggests that the Bill be amended so that the CEO is first required to consider submissions made by an approved prescriber on any contemplated or proposed administrative action prior to their relevant professional board being notified.

It may be that there may be information, not known to the CEO, which an approved prescriber could put to them which may impact on the decision whether to inform a Board.

Such a process would avoid the possibility of unnecessary referrals.

2.13 Section 166 – Notifying public about recall order

In addition to the public being notified about potential harm identified in a recall order, MIGA proposes that all prescribers known to be using the product identified in such an order be notified individually by Queensland Health, ensuring a timely dissemination of such information.

2.14 Section 172 – Membership of expert advisory panel

Given the evolving and controversial nature of medicinal cannabis treatment, MIGA considers that it would be appropriate to be more specific about the nature of the membership necessary for the expert advisory panel, particularly as such a panel will be considering personal and clinical suitability of health professionals and patients to be involved in such treatments.

In our view consideration should be given to including:

- lawyers experienced in both health care regulation and criminal law
- medical professionals who are specialists in the fields where medicinal cannabis use is contemplated, including oncology, neurology, palliative care and pain management
- medical ethicists, given the balancing of personal and clinical suitability for treatment

2.15 Chapter 9 – Reviews and appeals

MIGA respectfully submits:

- there is no basis to exclude the imposition of conditions on an approval from being subject to review and appeal, as seemingly contemplated by the description of an "*original decision*" under Section 179 of the Bill, particularly as the conditions may be such that the prescriber and patient consider that they do not achieve what was originally sought through the application, or cannot be complied with
- in circumstances involving urgency or a terminal illness, there should be scope for either expedited delivery of internal review applications and / or scope for a direct approach to the Queensland Civil and Administrative Tribunal on appeal

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2.16 Sections 212 and 214 – Disclosure for medicinal cannabis approval / CEO information requests

MIGA is concerned about the potential for uncertainty in what information a patient-class prescriber can provide to the CEO if requested, particularly as there is contemplation in Section 52 of the Bill to imposition of conditions on patient-class prescribers to notify the CEO of certain events.

Section 209 of the Bill sets out a variety of circumstances in which information may be appropriately disclosed. However, it does not directly deal with requests for information by the CEO. Section 212 only addresses this issue as it may affect single patient prescribers.

The Section 217 regulation-making power, including notification and reporting, may be insufficient to permit regulations being made in relation to all potential types of CEO requests for information.

It would be preferable for it to be made clear in the bill that confidential information may be disclosed to the CEO by a patient-class prescriber if requested.

Given this is a new and unique regime, MIGA foresees its members and other health professionals may need for legal advice on issues relating to their compliance with the proposed regime. Although there may be arguments that such information could be released to a legal advisor under Commonwealth privacy laws, for the sake of clarity it would be preferable that the Bill clearly state that single patient and patient-class prescribers can disclose confidential information for the purpose of seeking legal advice.

If you have any questions, please contact Timothy Bowen, Senior Solicitor – Advocacy, Claims and Education at [redacted].

Yours sincerely

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