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5 June 2019

Dr Jacqui Dewar
Committee Secretary
State Development, Natural Resources and
Agricultural Industry Development Committee
Queensland Parliament

Via email: sdnraidc@parliament.qld.gov.au

Dear Dr Dewar

MIGA Submission – Queensland Medicines and Poisons Bill

1. As a medical defence organisation and professional indemnity insurer, MIGA appreciates the opportunity to provide feedback on the Medicines and Poisons Bill 2019 (**the bill**) and the draft Medicines and Poisons (Medicines) Regulation 2019 (**the draft medicines regulation**).

2. MIGA's Submission focuses on issues around medication prescription and associated health care by doctors, other health practitioners and health care entities.

MIGA's interest and overall position

3. MIGA is generally supportive of the intent of the bill and draft medicines regulation, particularly to modernise and simplify medication prescription requirements, reflect technological improvements and to ensure a continuing high standard of health care in Queensland.

4. In particular, MIGA strongly supports the introduction of real-time prescribing systems for Schedule 8 and other potentially addictive medications throughout Australia. This is something which MIGA advocated for in various forums, including a recent Therapeutic Goods Administration consultation and Victorian parliamentary inquiry. It also contributed to the Victorian Health Department consultation on draft real-time prescribing regulations.

5. Significant education and training efforts will be needed to educate Queensland doctors, other health practitioners and health care entities around the new system, particularly real-time prescribing.

6. MIGA has concerns around a number of proposals, including offence provisions for prescription errors and self-prescribing, how the real-time prescribing system is intended to be used and obligations around use of electronic systems. It explores these issues below, setting out a range of alternative proposals.

7. MIGA's 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 insight into issues around prescription medication use. Its education initiatives include a recent interactive hypothetical session on medication prescription challenges, delivered across Australia, and recently developed interactive online education covering these issues. It has been advocating around prescription medication issues, including in the forums mentioned above and through key professional leader meetings it convened addressing the issue of opioid use. It also contributed to Queensland parliamentary inquiries on medicinal cannabis regimes.

8. Below is MIGA's feedback on the bill, draft medicines regulation and their implementation.

Introductory period for real-time prescribing

9. MIGA notes that a two year period is contemplated for a phased implementation of a real-time prescribing system, and that it may take more than 12 months before the system is operational (pp 87 to 88 of the bill's explanatory notes).

10. Consistently with the position in Victoria, MIGA supports an 18 month introductory period before use of a real-time prescribing system becomes mandatory for medical and other health practitioners. Given this is a new system for Queensland practitioners, time is needed for them to be educated and become familiar with what is required and what it involves.

Integration with other real-time prescribing systems

11. MIGA supports the Queensland Government making all possible efforts to ensure its real-time prescribing system can communicate and share information with other real-time prescribing systems throughout Australia under the National Data Exchange or otherwise.

Educational initiatives

12. As part of contemplated training and education for doctors, other health practitioners and health entities around both the real-time prescribing system and the new regime under the bill and draft medicines regulation more generally (see p 15 of the bill's explanatory notes), MIGA suggests that this be delivered in a variety of platforms (including face-to-face and online) and provide online resources for access as needed, including decision-making tools and case studies.

13. These education initiatives need to occur before the new regime comes into force so there is time for those regulated by it to be familiar with its obligations and operation before compliance becomes mandatory.

Offences for errors, self-prescribing and not checking real-time prescribing system

14. MIGA has significant concerns about a range of proposed offence provisions which could adversely affect doctors and other health practitioners who make unintended errors or are otherwise suffering from personal health issues.

15. Whilst it acknowledges there are a range of penalties under the current legislative regime, the proposed regime provides an opportunity to consider the necessity, appropriateness and fairness of these penalties, particularly for one-off errors and unintended breaches made in good faith by doctors and other health practitioners, and for their personal health issues.

16. MIGA opposes the following offence provisions
    - Prescribe, make standing orders or administer a medicine not in the authorised way without reasonable excuse – up to 200 penalty units, currently over $26,000 (ss 36 and 38 of the bill)
    - Self-prescribing or self-administering a high-risk medicine (including all Schedule 8 medications and a range of commonly used Schedule 4 medications) without reasonable excuse – up to 100 penalty units, currently over $13,000 (s 40 of the bill)
    - Failing to check the monitored medicines database (real-time prescribing system) prior to prescribing a monitored medication without reasonable excuse or not in situation prescribed by regulation (which are yet to be developed) – up to 20 penalty units, currently over $2,600 (s 41 of the bill)
    - Failure to comply with substance authority conditions without reasonable excuse – up to 200 penalty units, currently over $26,000 (s 71 of the bill).

17. In essence, these provisions create quasi-criminal penalties for unintended prescription errors and professional health issues. This is inappropriate. Whilst these issues must be avoided and dealt with as necessary, a Magistrates Court or other quasi-criminal process is not the right way to deal with them. Instead, they are matters for education, counselling and, where necessary, the involvement of professional regulators (such as the Medical Board of Australia) or civil damages claims.

18. MIGA considers the criminal law should only rarely intervene in the provision of health care. Any intervention should be restricted to extreme or exceptional cases, usually involving intentional or reckless conduct.

(a) Issues with offences for self-prescribing

19. MIGA has particular interest and experience in doctors' health issues, and considers that punitive penalty regimes for self-prescription are inappropriate. It sees this as effective criminalisation of a range of personal health issues.

20. The offence provision in s 40 of the bill would catch doctors who self-prescribe a range of commonly used prescription medications for treatment of pain and anxiety. Whilst self-prescription needs to be avoided, criminalisation of it is a step too far.

21. More broadly, there are significant issues relating to accessibility of appropriate health care for doctors, particularly around treating practitioner mandatory reporting,[1] issues of fear and embarrassment, and limitations posed by professional workloads.

22. For self-prescribing the better approach is support, education, counselling and, where necessary, involvement of the professional regulator, i.e. the Medical Board of Australia. There is a need to focus on ensuring Queensland doctors do not face barriers to accessing health care. MIGA welcomes opportunities to work with the Queensland Government and other professional stakeholders (such as the Doctors' Health Advisory Service (Qld) and other peak professional bodies) around these issues.

(b) Issues with offences for prescription errors

23. Turning to prescription errors, although the bill's explanatory notes (p59) indicate the 'authorised way' approach is meant to enable "*trained professionals to undertake their professional practice obligations without needing to list every authorised action in the legislation, with these professionals being sufficiently experienced and highly trained to know what the authorised way is when referring to particular activities*", this acknowledges that the 'authorised way' is based on general understandings, not necessarily clear standards. This provides clear scope for uncertainty and debate over what is appropriate professional practice and what is not. These are matters for disciplinary processes or civil claims where necessary, not a presumption of civil penalty and quasi-criminal proceedings.

24. Further uncertainty arises via ss 31, 54 and 91 of the bill and the draft medicines regulation (such as rr 23 to 44 and Schedule 6), which set out a range of detailed requirements around medication prescription. Accordingly the 'authorised way' is a mix of general understandings and detailed legislative requirements. This can be confusing and easily create the circumstances for an unintended breach of the regime in good faith.

25. Of particular note is that r 31 of the draft medicines regulation contemplates prescribing in accordance with departmental standards for monitored medicines. These are yet to be developed. Contemplating a civil penalty for breach of an as yet unknown standard is inappropriate.

(c) Existing penalty regime in professional regulation

26. Importantly for the perspective of public protection and ensuring proper health care standards, scope already exists under s 196 of the *Health Practitioner Regulation National Law* as it applies in Queensland for the Queensland Civil and Administrative Tribunal to impose a pecuniary penalty on a registered health practitioner of up to $30,000 in professional disciplinary proceedings following referral to a professional regulator.

27. This makes a separate penalty regime under the bill unnecessary.

(d) MIGA proposals

28. As set out above, MIGA seeks removal of the civil penalty provisions around medication prescription and self-prescription.

[1] MIGA has been involved in a range of consultations around treating practitioner mandatory reporting, most recently the Queensland Parliamentary inquiry into proposed treating practitioner mandatory reporting reforms – see www.migabulletin.com.au/article/two-very-different-ms-which-affect-you for further information, including links to MIGA's inquiry evidence and submission

29. Instead, the appropriate approach is one of education, counselling and, where necessary, referral to a professional regulator such as the Medical Board of Australia which can take appropriate action, including professional disciplinary proceedings seeking a pecuniary penalty in the most serious or extreme cases.

30. If the proposed offences are to remain under the new regime, MIGA seeks
    - For medication prescription for others
        - An approach towards compliance enforcement activities which involves counselling and education first, noting this is contemplated under the Victorian real-time prescribing system
        - Referral to the professional regulator (such as the Medical Board of Australia) should only be reserved for serious, or persistent, cases of regime breaches
        - Civil prosecution should only pursued where absolutely necessary, i.e. where the professional regulator cannot appropriately deal with the matter
        - Expanding the reasonable excuse defence around prescribing, making standing orders, medication administration and breach of substance authority, to a defence of reasonable belief in good faith of acting in the authorised way
        - Consistently expanding the reasonable excuse defence around not checking the monitored medications database to a defence of reasonable belief in good faith that checking was not required or otherwise impractical in the circumstances
        - Alternatively if the reasonable excuse defence is not widened, development of a consensus approach towards what is considered a reasonable excuse for prescription, making of standing orders or administration of medication in an unauthorised way, for breach of substance authority or not checking the monitored medicines database, with consequent guidance to and education for doctors, other health practitioners and health care entities
    - For self-prescribing
        - An approach of education and counselling first for one-off instances
        - Where necessary, early referral of cases to the profession regulator (i.e. the Medical Board)
        - Development of a consensus approach dealing with self-prescription or self-administration of medication which limits use of civil penalties to situations where professional regulatory processes are inadequate to deal with the issue
        - Further work with professional stakeholders such as MIGA around reducing barriers to doctors seeking care, and managing self-prescribing issues.

31. MIGA and other professional stakeholders should be involved in the development of each of these initiatives and approaches.

Public warnings

32. MIGA has reservations about the scope of the power to issue public warnings following notification action and proven offences under s 127 of the bill.

33. It supports a power to issue public warnings in limited, clear and compelling cases. This should only be where a significant risk cannot be remediated.

34. Where this involves a doctor or other health practitioner, it believes any need for this should be a matter for professional regulators, such as the Medical Board of Australia or other professional boards.

Purposes of monitored medicines database

35. MIGA is concerned at the broad scope of the objects of the monitored medicines database under s 224 of the bill.

36. It supports the database's objects involving promotion of safe practices, reducing community harm, enabling health practitioners to access the database for therapeutic purposes, and to facilitate monitored medication evaluation, research and national consistency in therapeutic use.

37. MIGA is troubled by the objects of ensuring health practitioner compliance with the new regime, corresponding laws or professional board requirements, and to assist the health ombudsman investigate complaints.

38. It accepts that the monitored medicines database may be a relevant tool for ongoing compliance activities, and a relevant information source in professional investigations.

39. However MIGA is concerned that setting compliance and investigation functions as objects of the database obscures its primary purposes of enhancing and improving health care. It sees this as introducing effectively a presumption that doctors and other health practitioners may not be discharging their legal and professional obligations. This can inappropriately influence the conduct of various regulatory bodies.

40. Where the monitored medicines database would be able to be used for compliance and investigative purposes in any event, these objects should be removed from s 224 of the bill.

Paper prescriptions sent electronically to pharmacist

41. MIGA questions the obligation under r 26 of the draft medicines regulation for a prescriber to telephone the pharmacist as soon as practicable, but no later than the next business day, to confirm the prescription.

42. Whilst it is necessary to ensure a prescription was received by a pharmacist, the requirement is unnecessary where the pharmacist has already confirmed receipt of the prescription, such as by telephone call or email to the prescriber.

43. MIGA proposes that r 26 be modified to only require a prescriber to telephone the pharmacist if they have not received acknowledgement from them by the next business day.

Electronic medication management systems

44. MIGA is concerned that the significant obligations in Chapter 5, Part 1 of the draft medicines regulation around electronic medication management systems and civil penalties for failing to meet those standards will operate as a disincentive to their use.

45. Whilst it endorses the need for appropriate privacy, confidentiality and security controls, it believes these matters are better dealt with under national and state privacy laws, such as the *Privacy Act 1988* (Cth) and the *Information Privacy Act 2009* (Qld).

46. Additional requirements as proposed in the draft medicines regulation may create confusion around how they relate to broader privacy and confidentiality obligations on doctors, other health practitioners and health care entities more generally.

47. Any breaches of privacy, confidentiality and security obligations around electronic medication management systems should be dealt with in the same way as under existing privacy and confidentiality regimes, not under a separate regime as the bill and draft medicines regulation contemplate.

48. You can contact Timothy Bowen, telephone [redacted] or email [redacted] if you have any questions about MIGA's Submission.

Yours sincerely

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