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From the President

25 January 2017

[redacted]

Via email: [redacted]

Dear [redacted]

Public Health (Medicinal Cannabis) Regulation 2017: consultation feedback

The Royal Australasian College of Physicians (RACP) thanks you for the invitation to provide feedback on the draft Public Health (Medicinal Cannabis) Regulation 2017 (*Regulation)*.

The RACP has consulted with its Medicinal Cannabis Reference Group and Queensland State Committee to develop this response. We would like to reiterate the concerns we have previously raised regarding the lack of a robust evidence base for medicinal cannabis and lack of a safe or reliably consistent supply for patients. As such, we are of the view that the proposed regulations are not strong enough. Patients deserve reliable, safe, and consistent products and, as with all medicines, high quality research needs to be supported before use, and growing and manufacturing must follow Good Manufacturing Practice (GMP).

Once again, we must express our disappointment at the very short consultation timeframe. While we appreciate that an extension was granted, such short deadlines are simply inadequate for meaningful consultation with expert stakeholders.

However, we make the following recommendations on the draft *Regulation* based on the feedback we were able to obtain in the limited time provided:

- Section 6: The definition of the term 'approval' should be reviewed, as medical practitioners usually understand 'approval' as referring to the approval of drug availability.
- Sections 13(d), 15, and 16: Manufacturing should satisfy GMP to ensure safety and consistency.
- Section 22(b): This section does not contain sufficient safeguards. Manufacturing and supply of cannabinoids requires a safe chain of handling to ensure safety for patients, due to the potential for illicit use and tampering with the product.

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- Section 41: An adverse reaction in a patient using cannabinoids should warrant investigation as part of the pharmacovigilance of cannabinoids, and should be included in this list of grounds for the chief executive to take administrative action.
- Section 49: The RACP notes that there is currently insufficient data to indicate under what circumstances, if any, it is safe for patients using cannabinoids to drive.
- Section 49(e): Approvals should be under relevant Therapeutic Goods Administration (TGA), Queensland *Health (Drugs and Poisons) Regulation 1996* and *Health Regulation 1996*, and patients should also have exhausted currently available evidence based treatment options prior to approval. It should also be noted here that the prescribing of medicines should be within prescribing guidelines. The RACP is concerned that doctors may be subject to significant pressures to prescribe medicinal cannabis, similar to the pressure to prescribe opioids, and the *Regulation* must support them to make good medical and ethical decisions.
- Section 52(1): Prescribed specialist medical practitioners should include all specialists in the conditions eligible for prescription of medicinal cannabis – for example, rheumatologists and general physicians have been omitted from the list. In order to ensure that all Fellows of the Australasian Chapter of Palliative Medicine are included, the wording of 52(1e) should be changed to "Specialist in palliative medicine".
- Section 56: Prescribed persons administering medicinal cannabis to patients in the care of an institution need to receive education on the cannabinoid and its administration prior to being authorised to administer medicinal cannabis, and be required to use a Schedule 8 record book. They should also be required to undergo a drug history check.
- Section 57: Greater restrictions and specificity are required here so that in hospitals only medical practitioners can prescribe medicinal cannabis and only nurses with appropriate training and authorisation to administer scheduled medications can administer medicinal cannabis.
- Section 62(2)(d): Following oral instructions to administer or supply the medicinal cannabis to the patient at the hospital, it should be mandatory for the doctor to provide written instructions at the earliest opportunity.

Overall, greater pharmacovigilance needs to be included in the regulations including accountability to monitor the outcomes. This is to ensure that adverse events, side effects and outcomes are accurately recorded to create an evidence base for the use of medicinal cannabis.

Should you require any further information about this matter, please contact [redacted] Policy Officer, on [redacted]

Yours sincerely

[redacted]

Dr Catherine Yelland PSM
RACP President

[redacted]

Dr Peter Davoren
Chair, Queensland Committee