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From the President

31 January 2017

[redacted]

Via Email: [redacted]

Dear [redacted]

Patient access to medicinal cannabis in South Australia: consultation feedback

The Royal Australasian College of Physicians (RACP) thanks you for the invitation to provide feedback on the *Patient access to medicinal cannabis in South Australia* discussion paper.

The RACP consulted with its Medicinal Cannabis Reference Group and South Australian State Committee. We would like to state the RACP's fundamental concerns regarding the lack of a robust evidence base and clinical testing for medicinal cannabis, which you acknowledge on your discussion paper. Patients deserve reliable, safe, and consistent products, and as with all medicines, high quality research needs to be supported before use, to determine product safety and suitability.

Our response to this consultation should not be seen as tacit support of access to medicinal cannabis outside of clinical trials and the regulatory regimes applied to other medicines, rather it represents an attempt to mitigate the potential harms. It should also be noted that there is a large opportunity cost to implementing these frameworks for medicinal cannabis when there is insufficient evidence to support its application. This can have the unintended consequence of diverting time, energy and financial resources away the provision of established evidence based care.

The discussion paper's Option Three presents the more appropriate approach to introducing a medicinal cannabis patient access pathway by seeking to restrict prescription to pharmacological agents governed by Schedule 8 and Therapeutic Goods Administration (TGA) of unregistered medicines regulations.

The following recommendations on the proposed patient access pathway are proposed based on the feedback we received from our expert groups:

- The RACP holds that any access to prescribed medicinal cannabis should be under a very restrictive framework, due to the poor body of data indicating any efficacy,

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safety or cost efficacy for medicinal cannabis for any indication. Drug diversion and minimising risks of harm (especially in young people), are managed best when access is tightly controlled.

- Prescription of therapeutics should be evidence based. Given the absence of robust evidence supporting the use of medicinal cannabis, any prescribed medicinal cannabis data under the proposed framework should be collected via clinical trials, registry or otherwise to expand the evidence of medicinal cannabis applications.
- Until there is robust evidence to support the prescribing of medicinal cannabis, section 18A authority should be restricted only to physicians and paediatricians.
- There is a need for the dosing of prescribed medicinal cannabis to be standardised through the use of pharmacological preparations.
- The inclusion of an expert clinical advisory panel is welcomed by the RACP. Further to the clinicians and experts in relevant fields already listed, the RACP recommends that an addiction medicine specialist is included. Preference and consideration should be given to restricting prescribing to physicians/paediatricians with special expertise in the condition being referred to treat, e.g. paediatric neurologists for childhood epilepsy or adult neurologists for multiple sclerosis.
- The term "specialist medical practitioners" needs to be clarified to determine if it refers to physicians or any medical practitioner with a specialty (e.g. general practitioners are specialists in general practice).
- The discussion paper does not address the prescription or use of medicinal cannabis to minors. As paediatric epilepsy and oncology are eligible conditions for medicinal cannabis to be prescribed, it would be prudent to address them.
- The flow chart (page 11) needs amending to correctly illustrate the proposed process:
    - The dashed arrows need to be moved from the "formal appeals mechanisms" box so they feed back to the "Application is assessed" box. This needs to change for both pathways.
    - There needs to be a line going to a "Patient review" box following the "Pharmacy dispenses medicinal cannabis" box. This is to ensure the patient is reviewed after medicinal cannabis is prescribed to determine whether the treatment is effective or not, to address any side-effects and determine whether it should be continued.

Lastly, involving physicians and the RACP in the process of developing medicinal cannabis guidelines and regulations is an important necessity considering our members' expertise managing the medical conditions involved. To take full advantage of this expertise and to ensure appropriate and adequate consultation takes place, the Department of Health and Ageing need to provide more realistic timeframes for consultations.

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

Yours sincerely

[redacted]

Dr Catherine Yelland PSM
RACP President

[redacted]

Dr Robert van den Berg
Chair, South Australia Committee