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Submission to Parliamentary Committees of the Queensland Parliament

Postal Address: *Public Health Committee*

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Regarding the Inquiry into the Public Health (Medicinal Cannabis) Bill 2016

The two authors of this submission write as both senior physicians in the public health system (Newcastle and Melbourne) with experience in Clinical Pharmacology, a medical specialty with expertise in all aspects of pharmaceutical design, development, clinical use and medicines regulation, and Addiction Medicine. Both authors are Fellows of the Royal Australasian College of Physicians but are not writing on behalf of that organization. JM has undertaken regulatory consulting work for the Therapeutic Goods Administration but is not speaking for that organization.

*The document below thus reflects their professional knowledge; it does not reflect any personal thoughts on this matter, nor any discussion about related, but confounding, topics which are legalised cannabis and recreational use of cannabis. Many of our thoughts are more formalised in a recent published manuscript: Perspectives in the Medical Journal of Australia "***Medicinal cannabis in Australia – the missing links", 2016.**

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Major Points for the Committee to Consider

There remain a number of clinical (safety and efficacy), regulatory, commercial, educational/training hurdles to overcome before patients can safely access medicinal cannabinoids. We believe that these hurdles can be appropriately and effectively addressed in a stepped, informed manner.

1. **Cannabis and cannabinoids.** We recommend that the Inquiry consider both cannabis and other cannabinoids, as patients use a variety of these. Several types of cannabinoids on the market have significant side effects (for example delta-9 THC) and some forms appear to be more palatable than others (for example tablets/capsules are the preferred delivery mode (n=144, 71%) documented in a recent palliative care study (Luckett T et al, in submission). Different forms of medicinal cannabis will be applicable to different conditions. For example, tetrahydrocannabinol (THC) may have a role for analgesic, anti-emetic, anti-oxidant and anti-inflammatory purposes. Cannabidiol on the other hand may have application in type II diabetes, inflammatory bowel disease, epilepsy, schizophrenia and other psychotic disorders. As well as different cannabinoids, and different modes of administration, the committee should consider synthetic vs. plant based cannabinoids.

2. **Safety and effectiveness data.** Unlike cannabis for recreational drug use, which we are not addressing in this document, the use of cannabis in human disease should be treated as a 'therapeutic good'. As such, a large amount of safety and effectiveness data is required to ensure the appropriate and least harmful use of this substance in different patient populations.

3. **National Framework.** Any legislation pertaining to medicinal cannabis should fit within a national framework, rather than within different State-by-State legislation. This would ensure that medicinal cannabis works within a national poisons and regulatory framework (e.g. Therapeutic Goods Administration). However national leadership is currently lacking in this area and therefore States are pursuing local solutions in response to increasing consumer pressure to make medicinal cannabis available as soon as possible.

4. **Clinical Regulatory Aspects:** Any changes to statewide formulary (I.e. the formulary overseen by the Queensland Health Medicines Advisory Committee) will mandate clinically relevant (i.e. human, in specific disease states) data on indications, efficacy,

safety and dose range of cannabinoids prior to enabling doctors to prescribe these in the public health system. It should be noted that some cannabis products (e.g. botanical leaf extract) contain more than one cannabinoid, and several cannabinoids are metabolised to compounds that may also be active. Other cannabinoids may consist of one molecule only, similar to current 'therapeutic goods' on the market. How different molecules and combinations of molecules affect disease states in different populations is at this stage still unknown.

5. **Safety data.** Safety data should be collected as for other drugs used in human disease. For example, it is important to determine the molecule's preclinical toxicity, safety for use in humans, basic physiochemical processes (i.e. stability over time and in different physical circumstances (e.g. is the product affected by Queensland humidity?), drug dissolution in the body, basic and clinical pharmacokinetics and efficacy.

6. **Devices**. Medical devices for administration (e.g. devices for vaporisation) also need to be assessed for their safety and applicability to medicinal cannabis.

7. **Clinical Data**. Clinical data on one population group, disease type, and mode of cannabis is needed because it is likely to differ when used in other diseases or conditions. Analogies with other therapeutic goods are available. For example, valproate is used at one dose range in children, and in different dose ranges in adults, depending on if it used for depression, chronic pain, migraines or epilepsy. Monitoring of valproate is required for the significant side effects that occur in different patient groups. Medicinal cannabis will be likely to require similar dose adjustments and monitoring for the wide range of conditions for which it will potentially be of benefit.

8. **Consistency of Product**. Working with the national regulator, prescribers and patients will be likely to feel more comfortable that drug constituents are consistent and of high, reproducible quality. It covers the different pharmacology of different parts of plant and its species, batch variation (e.g. differences between cultivation sites or over time). The relative benefits of prescribing plant-derived molecule versus laboratory synthesized cannabinoids need to be determined and quantified. Lastly, safety and regulatory aspects of cannabinoids from a range of different (mostly domestic) sources that are sent to pharmacies to be compounded for patients will need careful consideration and policy consideration.

9. **Dispensing issues.** These include how the drug will be dispensed, prescribed, monitored and issues around medical supply of a potentially abusable substance. Depending on the underlying condition, decisions will need to be made regarding whether one month (e.g. palliative care context) or shorter (e.g. chronic pain context) supply can be provided because of the potential for stockpiling of the medication.

10. **Restriction of access.** Restriction of access to medicinal cannabis by authorised medical practitioners is likely to be required, particularly in the first few years of availability of medicinal cannabis. Restriction of prescribing to a specific group or individual, such as Palliative Care, Pain or Addiction Medicine practitioners will be important especially in the early stages of prescribing while the clinical experience is accumulating. In other contexts, access can be restricted to clinical trials conducted under the TG Act when unapproved products such as these are used i.e. Clinical trial Notification or Clinical Trial Exemption, and supply as an unapproved product through the TGA Special Access Scheme Category B or an Authorised Prescriber scheme. The NSW Government has had a compassionate access scheme since 2014 and the Victorian Government is also developing a scheme to provide patients with access to medicinal cannabis.

11. **Education**. Implementation of medicinal cannabis will require education and training for medical practitioners and other health professionals. Experience shows that in Canada, doctors are 'gatekeepers' for medicinal cannabis, but lack of research and guidance from authorities has resulted in many declining to prescribe it, despite that most doctors actually support its public health aspects (1). A 2016 survey by the Royal Australasian College of Physicians on medicinal cannabis showed similar findings with the three main issues raised by Fellows of the College being: 1) the need for training resources 2) concerns that patients and families/carers may have unrealistic expectations and 3) concern about the lack of evidence for the efficacy of medicinal cannabis including its efficacy compared to other available therapeutics. Such training will be required for medical practitioners, pharmacists and other health professionals to minimise inappropriate prescribing and drug diversion. Looking ahead, curricula in medical school and other undergraduate courses in the health professions, already relatively devoid of formal structured Clinical Pharmacology and Addiction Medicine teaching, will need to include education and training with regard to

cannabis. Collaboration, for example with the Australian Medical Council and Medical Deans of Australia and New Zealand will be needed to address these issues.

Closing Comments

Disease symptoms are not new; for most conditions for which patients are requesting access to medicinal cannabis, there are already several safe and effective registered therapeutic goods available. Notwithstanding this, medicinal cannabis poses an exciting potential new agent in the pharmacotherapeutic armamentarium and this should be explored.

Experience in providing access to potential drugs of abuse and previous examples of medicinal products that have been misused or abused (e.g. the exponential rise in oxycodone prescribing in the community (2), abuse of benzodiazepines such as alprazolam, misuse of antipsychotics etc) should be heeded and should assist in guiding the journey to appropriate regulation and roll out of medicinal cannabis, as long as pressure from the community for immediate access to cannabis is appropriately managed.

Finally it is recommended that on any Advisory Committee, both a Clinical Pharmacologist and a Addiction Specialist are included. Allied Health practitioners in the area of pharmacy – both public hospital and community would also be recommended.

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2. Roxburgh, A. (2011). Prescription of opioid analgesics and related harms in Australia. *The Medical Journal of Australia* **195**, 280-284.