The Royal Australian & New Zealand College of Psychiatrists

18 March 2015

Ms Sophie Dunstone
Committee Secretary
Senate Legal and Constitutional Affairs Legislation Committee
PO Box 6100
Parliament House
CANBERRA ACT 2600

By email to: legcon.sen@aph.gov.au

Dear Ms Dunstone

Re: Inquiry into the Regulator of Medicinal Cannabis Bill 2014

The Royal Australian and New Zealand College of Psychiatrists (RANZCP) welcomes the opportunity to provide feedback to the Senate Legal and Constitutional Affairs Legislation Committee's Inquiry into the Regulator of Medicinal Cannabis Bill 2014 (the Bill).

The Bill aims to establish an independent regulator (the Regulator) that would be responsible for licensing the growing, manufacturing and distribution of medicinal cannabis. The Regulator's role would be to approve medicinal cannabis products for inclusion in a register that will operate separately from the Therapeutic Goods Administration. To be included on the register, the Regulator must be satisfied that the cannabis product is suitable for medicinal use and that it meets all appropriate standards. In this way, the Bill aims to ensure that medicinal cannabis is manufactured, supplied and used in a safe and controlled way.

The RANZCP welcomes the motivation of the Bill, which is based on the idea of improving the quality of life of certain patient populations through the use of medicinal cannabis products that have an evidence base to support their use. The RANZCP also supports conducting research into cannabis as a potential substance for therapeutic use and – if legitimate medical uses are established – then considers it is appropriate for cannabis to be utilised for those purposes.

However, the RANZCP considers that caution must be exercised as cannabis is a substance that may cause significant psychiatric morbidity and can alter the trajectory of an individual's mental illness for the worse. To that end, the RANZCP is concerned that – if the proposed Bill were to become law – it does not have a provision to register patients who have had psychiatric sequelae to cannabis use. Without such a register, there would be the potential for medical practitioners to prescribe something that – while it may be the appropriate treatment for a medical concern - could have a significant detrimental impact on a person's mental health and would not be in the best interests of both patients and prescribers.

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Further, the RANZCP believes it is important for the Committee to be aware of the current anecdotal nature of the available evidence of cannabis for medicinal use, the lack of research characterising individual components of the botanical drug and the variation in the proportions of these components in the various cultivars - notably, the 'recreational' varieties have been selected for psychotropic effect and not for other purported effects such as anti-nausea. Cannabis used for medicinal purposes may also be a potential risk to children and young people as illustrated by the evidence of psychotogenic or hallucinogenic effects in certain age groups.

The RANZCP Tasmanian Branch made a submission to the Tasmanian Legislative Council's Inquiry into legalised medicinal cannabis in August 2014, which covers these issues in more detail. A copy of that submission is attached for the Committee's information.

If you would like to discuss any of the issues raised in this submission, please contact Rosie Forster, Senior Manager, Practice, Policy and Partnerships via

Yours sincerely

Dr Murray Patton
President

Ref: 3993

The Royal Australian & New Zealand College of Psychiatrists
Tasmanian Branch

SUBMISSION TO LEGISLATIVE COUNCIL INQUIRY INTO LEGALISED MEDICINAL CANNABIS

1. Efficacy and safety of natural botanical medicinal cannabis flower and extracted cannabinoids for medical purposes.

Extracts and tinctures of cannabis were in lawful medicinal use until the 1950s, although by that time their use had become uncommon as they were largely rendered obsolete by more specific drugs. A standard statement on the medicinal use of cannabis at the time betrays the non-specific nature of the effects of the drug, and notably it does not mention one of the principal purposes for which it is currently advocated: nausea in association with cancer and cancer treatment.

> The drug has been used medicinally for 2,000 years. It has been given with success in migraine and neuralgia, but it very often fails to afford relief. It is used for depressive mental conditions and anxiety states notably when associated with duodenal ulcer. It is useful for insomnia associated with pain because it combines analgesic with soporific action.
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> [*Hale-White's Materia Medica, Pharmacology and Therapeutics*, 30th edition. London: J & A Churchill 1957, p. 177]

The quoted passage represents a summary of the state of knowledge concerning the therapeutic use of cannabis towards the end of its availability as a lawful prescription drug. Only the last-mentioned indication (insomnia associated with pain) is now one of the purposes for which its lawful availability is advocated.

The efficacy of the drug for any purpose has not been investigated by modern systematic methods. The extracts formerly used, and the preparations currently in unlawful use, contain a number of different pharmacologically active substances in varying proportions, and each of these needs to be adequately characterised and assessed as to its effects and possible toxicity.

There have been a number of anecdotal reports, some receiving wide publicity in the public media, of the efficacy of cannabis preparations, some in uncommon conditions. These cannot be regarded as scientific evidence sufficient to justify their lawful prescription. No new drug enters the lawful pharmacopeia without rigorous scientific testing concerning its safety and efficacy. In the present state of the law, such testing cannot lawfully be carried out with preparations derived from natural cannabis. Until that becomes possible, no scientifically valid claim concerning the efficacy of cannabis derivatives in any condition can be made.

In the present state of knowledge, the efficacy of the natural combinations of drugs and of the individual drugs is largely unknown, and their safety uncertain.

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2. **If, and how, natural botanical medicinal cannabis flower and extracted cannabinoids could and/or should be supplied for medicinal use.**
There is much evidence that the majority of the cannabis grown and sold for unlawful use is now derived from seed stock selected for a relatively high yield of tetrahydrocannabinol (hereafter THC), the principal psychoactive component of cannabis that produces the euphoriant and psychedylic effects desired by 'recreational' users. It would appear that as a consequence, current unlawful supplies contain a relative lack of substances that mitigate the tendency of THC to produce psychotic reactions, and perhaps, in susceptible adolescents to precipitate schizophrenia.

It is also possible that the desired anti-nauseant and analgesic-sedative properties for which medicinal cannabis is now being advocated are substantially due to substances other than THC.

The proper investigation of medicinal cannabis should be applied to plant stock that has not been selected for high THC yield.

Cannabis products taken by inhalation as smoke are highly irritant to the lungs, whether alone or in combination with lawful tobacco, so appropriately standardised oral preparations should be the aim of those advocating medicinal cannabis.

3. **The legal implications and barriers to the medicinal use of natural botanical medicinal cannabis flower and extracted cannabinoids in Tasmania.**
If legitimate medical uses are established, the drug should be controlled under the Poisons Act, with a comparable level of control to opioid narcotics. The legitimate usage is likely to become comparable to that of opiate analgesics if pain plus insomnia becomes a recognised indication in addition to nausea associated with cancer and cancer treatment. There may be advocates who will claim the comparative safety of cannabis, but the risks of diversion to unlawful use and adverse mental disturbances are comparable.

4. **The legal implications and barriers to the growing and commercialisation of cannabis flower and extracted cannabinoids in Tasmania to ensure:**

(a) a scientific-based approach:
The existing legal restrictions on the use of cannabis around the world have largely prevented research on the various chemical substances produced by the cannabis plant. If considering legalising prescription cannabis, the Tasmanian Government should at least commission an authoritative review of research publications on cannabis and related topics produced during (say) the last twenty years.

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(b) quality control, (c) consistency and (d) reliability
When cannabis extracts and tinctures were used in the past, it is probable that their potency and the proportions of the various active substances contained in them varied considerably. The problem for research and therapeutic use will be to produce preparations that are at least as well standardised as the few plant extracts currently used in the orthodox medical pharmacopeia. A standard used by the alternative therapeutic community will not necessarily suffice.

(e) ongoing research and development of cannabis-based medicines
This will necessitate the lawful growing and production of botanical cannabis leaf and flower, with appropriate controls and restrictions on this.

5. The potential impact on agricultural and other sectors within Tasmania
The problem of theft from lawful crops and the diversion of cannabis plant products (seeds, leaves, flowers and resin) is likely to be considerably larger than is currently the case with opium poppies, because of the widespread use and partial tolerance of cannabis use in the community, and its reputed lower toxicity, particularly as compared with thebaine-producing poppies.

6. Any other matters incidental thereto
It is the experience of many psychiatrists that patients who express a wish to obtain cannabis lawfully are motivated more by experience of its 'recreational' use than by reputed target symptoms that they may have, or claim to have. The alleged benefits of cannabis (some of them unproven) have been widely promulgated, and for doctors, the problems of assessment and control will probably be comparable to those associated with the prescription of opioids.

- There is a very small but persistent fraction of the medical profession who appear to be open to indulging the demands and requests of patients for drugs of dependency where there is not adequate clinical reason for their prescription. The availability of 'medical cannabis' is likely to increase such demand considerably, and there may be a risk of some increase in the sources of supply.

If valid research shows that cannabis-derived drugs provide undoubted benefit to patients, concerns about a 'slippery slope' to full legalisation of cannabis should not outweigh this. However, in their deliberations on the subject, the members of the Committee should consider the community-wide consequences of a relaxation of the current prohibitions on cannabis use.

- There is accumulating evidence that cannabis use, at least in adolescence, is associated with an increased risk of developing schizophrenia.

- In sufferers from schizophrenia and related psychoses, use of cannabis frequently exacerbates symptoms and makes treatment less effective.

- Cannabis use by drivers increases the risks of road transport.

Further

- There is a lucrative, albeit unlawful, industry in the production and distribution of cannabis. Its legalisation would not only create new legitimate enterprises, but it would also lead those accustomed to the present income from cannabis to divert their energies to even more harmful activities. The dangers of 'decriminalisation' are well illustrated by a study of the consequences of the repeal of Prohibition in the United States; it is arguable that much of the present trade in unlawful drugs in Western societies and beyond is a consequence of the diversion of effort by criminal organisations deprived of their lucrative trade in unlawful alcohol. Prohibition of alcohol (and of cannabis) may have been an unwise and unenforceable policy, but there is a need to consider the likely consequences of the removal of such restrictions.

Prepared by:

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