AMA Victoria submission to Victorian Law Reform Commission on *Medicinal Cannabis Issues Paper*

AMA Victoria welcomes the opportunity to provide comment on the Victorian Law Reform Commission's review of the law in relation to medicinal cannabis.

AMA Victoria was honoured to be invited to attend the first meeting of the Victorian Law Reform Commission's Medicinal Cannabis Advisory Committee.

In the following submission AMA Victoria responds to questions posed in the Agenda of the Advisory Committee meeting held on Wednesday 1 April 2015, with reference to the Medicinal Cannabis Issues Paper.

Determining who may be treated with medical cannabis

The Victorian Law Reform Commission (VLRC) states in its Issues Paper (p 49) that 'a scheme that makes cannabis available 'in exceptional circumstances' for persons with particular health needs should be driven by compassionate considerations which provide treatment options that are not wholly established by orthodox double-blind, placebo-controlled trials'.

AMA Victoria supports legalisation of medicinal cannabis to treat people in certain controlled medical circumstances only where evidence, safety and law reform are key considerations. We also note that smoking or injecting a crude plant product is harmful, and regular inhalation of cannabis can increase the risk of lung damage, and cause higher rates of psychotic illness.

AMA Victoria encourages the government to address the state of clinical knowledge and conduct further clinical controlled trials to establish what diseases and conditions medicinal cannabis can effectively treat, what dosage levels are required, and the mode of delivery. AMA Victoria considers this to be the primary consideration to ensure that no harm comes to patients as a result of using a substance, the efficacy of which is currently not evidence-based.

The VLRC Issues Paper states (p 50) that 'departure from the principles of evidence-based medicine should only take place where the potential benefits outweigh the potential risks, dangers and side effects'. AMA Victoria has concerns about this statement, and notes that there should be no exceptional circumstances or 'compassionate considerations' where medicinal cannabis is used to treat a patient until such use is evidence-based. Medical practitioners cannot currently effectively weigh up unsubstantiated benefits, risks, dangers and side effects of medicinal cannabis.

In addition, AMA Victoria has concerns about terminology or concepts such as 'compassionate' or 'exceptional' circumstances, which are vague, subjective terms and are likely to lead to a lack of clarity in medical practice.

Risks and side effects

There is some evidence to suggest that cannabinoids are effective for the treatment of neuropathic pain, muscle spasticity for patients with MS, and in controlling nausea for cancer patients. The majority of this evidence involves pharmaceutical preparations rather than crude cannabis. There is limited evidence on the long term effects of medicinal cannabis.

Therapeutic cannabinoids that are scientifically evaluated to be safe and effective should be made available to patients for whom existing medications are not as effective. However, approval for these

treatments must be subject to the same regulatory and quality control processes that are applied to other medicines in Australia.

AMA Victoria supports addressing the state of clinical knowledge and conducting further clinical controlled trials to establish what diseases and conditions medicinal cannabis can effectively treat, what dosage levels are required, and the mode of delivery.

AMA Victoria does not support the use of crude cannabis for medicinal purposes. In addition to the regulatory complexities that this would involve:

- few clinical trials have been undertaken on crude cannabis, and there is a lack of evidence to demonstrate its efficacy for a particular indication;
- the potency and safety of crude cannabis is unknown, variable and unregulated;
- there are serious concerns about the safety of smoked cannabis, and smoking or ingesting a crude plant product is a harmful way to deliver cannabinoids for medical purposes. Other appropriate ways of delivering cannabinoids for medical purposes should be developed.

Pharmaceutical preparations of cannabis have greater potential to be delivered safely and can be subject to rigorous regulatory control, both in their preparation and administration, thereby reducing the potential for harm both to the user and the wider society.

Where the patient already has a terminal illness, AMA Victoria advocates that terminally ill patients should not be administered medicinal cannabis prior to clinical testing nor should the potential risks or negative side effects produced by the 'compassionate' use of cannabis be disregarded merely because of a patient's age or health status, such as approaching the end of life. AMA Victoria is concerned that providing terminally ill patients with medicinal cannabis before it has been confirmed as clinically safe, and solely based on the patients' end of life status, diminishes the value of the lives of the terminally ill.

Additionally, the Issues Paper states (p 31) that claims have been made as to the efficacy or potential efficacy of cannabis as 'a treatment for a range of psychiatric disorders, including post-traumatic stress disorder and a number of psychotic disorders'. AMA Victoria is similarly wary of the use of cannabis in psychiatric care where the efficacy has not yet been proven, particularly in light of links between cannabis and psychological side effects including psychosis-like symptoms in some patients. AMA Victoria acknowledges the increasing evidence that regular cannabis use precedes and causes higher rates of psychotic illness. If a patient has a predisposition to a psychotic illness, such as schizophrenia, cannabis may trigger the first episode in what can be a lifelong, disabling condition.

Applying eligibility criteria

AMA Victoria encourages a coordinated and consistent federal approach to legislative reform and regulation of medicinal cannabis, rather than a state-by-state approach.

AMA Victoria foresees that where a specific statutory list of the conditions or symptoms for treatment by cannabis is introduced, problems may arise in practice where the list of applicable conditions may fail to correspond with developments in clinical trials.

As an alternative, AMA Victoria recommends relying on the same framework in section 34 of the *Drugs, Poisons and Controlled Substances Act 1981* that relates to Schedule 8 poisons. Medicinal cannabis could be added to the list of drugs, poisons and controlled substances within this existing legislative framework.

The regulations that list the different and changing forms of controlled drugs are currently regularly updated without the need for extensive legislative reform processes, and could accommodate the different forms of medicinal cannabis if they are clinically approved in the future.

Using this existing framework also promotes administrative consistency for practitioners who must know their own obligations with respect to new and controlled treatment options, and are already familiar with the Schedule 8 processes.

Authorisation and patient care

Once tested appropriately in clinical trials, AMA Victoria recommends that medicinal cannabis be processed and distributed as a Schedule 8 drug in Victoria subject to a permit and existing regulations for controlled substances, including strict administrative requirements. This would uphold a consistent approach to processing and distribution of controlled drugs and substances across Victoria.

AMA Victoria supports the role of medical practitioners as 'gatekeepers' as stated in the VLRC Issues Paper (p 136) where 'patients must receive approval from medical practitioners before they can access the product'. However, AMA Victoria acknowledges that in urban areas of Victoria and across Australia, it is becoming increasingly uncommon for a person to have a long-standing physician-patient relationship with a specific medical practitioner. Therefore, AMA Victoria does not support the Oregon model identified in the Issues Paper (p 136), where a physician may only authorise a patient's access to medicinal cannabis if they have met a set of physician-patient relationship requirements. AMA Victoria notes that the permit requirements outlined for Schedule 8 classified drugs and substances may be sufficient to authorise a patient's use of medicinal cannabis.

VLRC states in its Issues Paper (p 158) that part of the 'gatekeeper' role of medical practitioners involves advising patients about the advantages, disadvantages, options and risks of treatment'. AMA Victoria reiterates that medical practitioners are only able to conduct this crucial educational role as part of good medical practice, once conclusive clinical trials are conducted on the efficacy and side effects of medicinal cannabis.

Additionally, AMA Victoria recommends that any promotion of medicinal cannabis by the medical profession will require extensive public education to highlight the harmful effects of its non-medical use, including its correlation with mental illness.